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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1150

[Document No. AMS–DA–14–0074]

National Dairy Promotion and Research Program; Amendments to the Order

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule amends the Dairy Promotion and Research Order (Dairy Order). The amendment modifies the number of National Dairy Promotion and Research Board (Dairy Board) importer members. The total number of importer members would be reduced from 2 members to 1 member, and the domestic Dairy Board members would remain the same at 36. The Dairy Order requires that at least once every three years, after the initial appointment of importer members on the Dairy Board, the Secretary shall review the average volume of domestic production of dairy products compared to the average volume of imports of dairy products into the United States during the previous three years, and, on the basis of that review, if warranted, reapportion the importer representation on the Dairy Board to reflect the proportional shares of the United States market served by domestic production and imported dairy products.

DATES: *Effective Date:* August 12, 2016.

FOR FURTHER INFORMATION CONTACT: Whitney A. Rick, Director, Promotion, Research and Planning Division, AMS, USDA, 1400 Independence Ave. SW., Room 2958–S, Stop 0233, Washington, DC 20250–0233. Phone: (202) 720–6909. Email: *Whitney.Rick@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: This final rule is issued pursuant to the Dairy Production Stabilization Act (Dairy Act) of 1983 [7 U.S.C. 4501–4514], as amended.

Executive Order 12866

The Office of Management and Budget has waived the review process required by Executive Order 12866 for this action.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This final rule is not intended to have a retroactive effect. In accordance with 7 U.S.C. 4512(a), this rule will not preempt or supersede any other program relating to dairy product promotion organized and operated under the laws of the United States or any State.

The Dairy Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under 7 U.S.C. 4509, any person subject to the Dairy Order may file with the Secretary of Agriculture (Secretary) a petition stating that the Dairy Order, any provision of the Dairy Order, or any obligation imposed in connection with the Dairy Order is not in accordance with the law and request a modification of the Dairy Order or to be exempted from the Dairy Order. Such person is afforded the opportunity for a hearing on the petition. After a hearing, the Secretary would rule on the petition. The Dairy Act provides that the district court of the United States in any district in which the person is an inhabitant or has his principal place of business, has jurisdiction to review the Secretary's ruling on the petition, provided a complaint is filed not later than 20 days after the date of the entry of the ruling.

Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612), the Agricultural Marketing Service has considered the economic impact of this action on small entities and has certified that this final rule will not have a significant economic impact on a substantial number of small entities. The purpose of the Regulatory Flexibility Act is to fit regulatory actions to the scale of businesses subject to such actions so that small businesses will not be disproportionately burdened.

The Dairy Act authorizes a national program for dairy product promotion, research and nutrition education. Congress found that it is in the public interest to authorize the establishment of an orderly procedure for financing (through assessment on all milk produced in the United States for commercial use and on imported dairy products) and carrying out a coordinated program of promotion designed to strengthen the dairy industry's position in the marketplace and to maintain and expand domestic and foreign markets and uses for fluid milk and dairy products.

The Small Business Administration [13 CFR 121.201] defines such entities with fewer than 500 employees as small businesses. According to 2013 data from the U.S. Census Bureau, 98.6 percent of these types of firms had fewer than 500 employees (*http://census.gov/econ/subs/*). According to the U.S. Customs and Border Protection (CBP), in 2014, approximately 1,400 importers paid assessments under Section 1150.152(b) of the Dairy Order. Although data is not available concerning the sizes of these firms, it is reasonable to assume that most of them would be considered small businesses. The most common classification for dairy product importers is Grocery and Related Product Merchant Wholesalers (North American Industry Classification System, category 4244).

The final rule amends the Dairy Order, Section 1150.131(c), by reducing the number of Dairy Board importer representatives from 2 members to 1 member.

The amendment should not have a significant economic impact on persons subject to the Dairy Order. The changes allow representation on the Dairy Board to better reflect the volume of dairy product imports into the United States.

Paperwork Reduction Act

In accordance with the Office of Management and Budget (OMB) regulation [5 CFR part 1320] which implements the Paperwork Reduction Act of 1995 [44 U.S.C. chapter 35], the information collection requirements and record keeping provisions imposed by the Dairy Order have been previously approved by OMB and assigned OMB Control No. 0581–0093. No relevant Federal rules have been identified that duplicate, overlap, or conflict with this rule.

Statement of Consideration

Upon publication of this rule, the Dairy Order is administered by a 37-member Dairy Board, 36 members representing 12 geographic regions within the United States and 1 member representing importers. The Dairy Order requires in Section 1150.131(f) that at least once every three years, after the initial appointment of importer representatives on the Dairy Board, the Secretary shall review the average volume of domestic production of dairy products compared to the average volume of imports of dairy products into the United States during the previous three years and, on the basis of that review, if warranted, reapportion the importer representation on the Dairy Board to reflect the proportional shares of the United States market served by domestic production and imported dairy products. This reapportionment review is the first conducted since importer members were appointed to the Dairy Board on November 2, 2011.

For initial representation of importers on the Dairy Board, the Dairy Act states "In making initial appointments to the Board of importer representatives, the Secretary shall appoint 2 members who represent importers of dairy products and are subject to assessment under the order." 7 U.S.C. 4504(b)(6)(A). For subsequent representation of importers, the Dairy Act goes on to state "At least once every 3 years after the initial appointment of importer representatives under subparagraph (A), the Secretary shall review the average volume of domestic production of dairy products compared to the average volume of imports of dairy products into the United States during the previous 3 years and, on the basis of that review, shall reapportion importer representation on the Board to reflect the proportional share of the United States market by domestic production and imported dairy products." 7 U.S.C. 4504(b)(6)(B).

Section 1150.131(f) of the Dairy Order states the basis for the comparison of domestic production of dairy products to imported products should be estimated total milk solids. The calculation of total milk solids of imported dairy products for reapportionment purposes "shall be the same as the calculation of total milk solids of imported dairy products for assessment purposes." The reapportionment review was not conducted prior to 2015 because three full years' worth of data was not available.

Using National Agricultural Statistical Service (NASS) Annual Dairy Products Summary data, the average U.S. milk total solids for domestic dairy products for 2012 to 2014 was 23,462 billion pounds annually. Based on the total milk solids number, each of the 36 domestic Dairy Board producer members would represent 652 million pounds of total milk solids (23,462 billion pounds divided by 36 producer members equals 652 million pounds per producer).

Using information received from CBP, the average total milk solids imported during 2012 to 2014 was 589 million pounds (589 million pounds divided by 1 importer member equals 589 million pounds per importer).

Accordingly, Table 1 summarizes, based on U.S. total solids and imported total solids, the adopted number of Dairy Board seats for domestic and importer members.

TABLE 1—DAIRY BOARD REPRESENTATION BASED ON U.S. TOTAL SOLIDS AND IMPORTED TOTAL SOLIDS

	Average total milk solids (lbs.)	Adopted number of board seats	Average total milk solids represented per board member (lbs.)
Domestic Producer	23,461,555,556	36	651,709,877
Importer	589,296,653	1	589,296,653

On April 1, 2016, a proposed rule was published in the **Federal Register** [81 FR 18802] inviting comments on proposed modifications to the number of importer representatives on the Dairy Board. Interested parties were provided 30 days to comment on the proposed amendment. USDA received three timely comments from industry organizations and an individual. Of those comments, two were opposed the rule and one did not address the merits of the proposed rule.

One commenter opposed reducing the number of importer members on the Dairy Board, recognizing that approximately 1,400 importers paid assessments under the Dairy Order in 2014. The commenter stated that due to the limits of the Dairy Tariff-Rate Import Quota Licensing Program placed on the volume of cheese imported into the U.S., increasing import volumes by any appreciable amount is impossible.

A second commenter also opposed the proposal to reduce Dairy Board importer representation from two members to one member, and urged for the withdrawal of the proposed rule. The commenter recognized the Dairy Act requires importer representation to reflect the proportional share of the U.S. market by domestic production and imported dairy products. However, the commenter argued that increasing import volumes by any appreciable amount is impossible due to the limits placed on the volume of cheese imported into the U.S. by factors beyond the control of the market, namely quotas, tariffs and import licenses. The commenter also stated safeguard triggers require substantially higher tariffs if the triggers are breached and noted this occurred with butter in 2015 and may occur in the coming year with several cheeses. The commenter went on to state that the Trans-Pacific Partnership (TPP) and the Transatlantic Trade and Investment Partnership (TTIP) agreements are focused on the reduction, if not elimination of tariffs and quotas. As a result, TPP and TTIP implementation would likely result in an increase in imported dairy products, including cheese, and would make the representation of importers on the Dairy Board even more meaningful.

As noted in the proposed rule, the Dairy Order requires and provides instruction on how to carry out a review to determine whether or not a reapportionment of importer members on the Dairy Board is warranted. Therefore, the proposed rule will not be withdrawn. Neither commenter disputed the method of nor the data used to conduct the reapportionment review. Similarly, an alternative process for conducting the review was not offered. Additionally, because the Secretary is required to review importer representation every three years, any increase in imported dairy products, cheese or otherwise, would be reflected in the calculations used to determine whether importer representation would increase, remain the same, or decrease.

This final rule adopts the proposed rule without change, and therefore Dairy Board importer representation is decreased from two importer members to one importer member.

Pursuant to 5 U.S.C. 553, it is found and determined that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** because this rule should be in effect as soon as possible to appoint Dairy Board members for the 2016–2019 term.

List of Subjects in 7 CFR Part 1150

Dairy products, Milk, Promotion, Research.

For the reasons set forth in the preamble, 7 CFR part 1150 is amended as follows:

PART 1150—DAIRY PROMOTION PROGRAM

■ 1. The authority citation for 7 CFR part 1150 continues to read as follows:

Authority: 7 U.S.C. 4501–4514 and 7 U.S.C. 7401.

■ 2. In § 1150.131, paragraph (c) is revised to read as follows:

§ 1150.131 Establishment and membership.

* * * * *

(c) One member of the board shall be an importer who is subject to assessments under § 1150.152(b).

* * * * *

Dated: August 8, 2016.

Elanor Starmer,

Administrator.

[FR Doc. 2016–19140 Filed 8–11–16; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 56, 145, 146, and 147

[Docket No. APHIS–2014–0101]

RIN 0579–AE16

National Poultry Improvement Plan and Auxiliary Provisions

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the National Poultry Improvement Plan (NPIP), its auxiliary provisions, and the indemnity regulations for the control of H5 and H7 low pathogenic avian influenza. Specifically, we are clarifying who may participate in the NPIP, amending participation requirements, amending definitions for *poultry* and *breeding stock,* amending the approval process for new diagnostic tests, and amending slaughter plant inspection and laboratory inspection and testing requirements. These changes will align the regulations with international standards and make them more transparent to Animal and Plant Health Inspection Service stakeholders and the general public. The changes in this final rule were voted on and approved by the voting delegates at the Plan's 2014 National Plan Conference.

DATES: Effective September 12, 2016.

FOR FURTHER INFORMATION CONTACT: Dr. Denise Brinson, DVM, Director, National Poultry Improvement Plan, VS, APHIS, USDA, 1506 Klondike Road, Suite 101, Conyers, GA 30094–5104; (770) 922–3496.

SUPPLEMENTARY INFORMATION:

Background

The National Poultry Improvement Plan (NPIP, also referred to below as "the Plan") is a cooperative Federal-State-industry mechanism for controlling certain poultry diseases. The Plan consists of a variety of programs intended to prevent and control poultry diseases. Participation in all Plan programs is voluntary, but breeding flocks, hatcheries, and dealers must first qualify as "U.S. Pullorum-Typhoid Clean" as a condition for participating in the other Plan programs.

The Plan identifies States, flocks, hatcheries, dealers, and slaughter plants that meet certain disease control standards specified in the Plan's various programs. As a result, customers can buy poultry that has tested clean of certain diseases or that has been produced under disease-prevention conditions.

The regulations in 9 CFR parts 145, 146, and 147 (referred to below as the regulations) contain the provisions of the Plan. The Animal and Plant Health Inspection Service (APHIS, also referred to as "the Service") of the U.S. Department of Agriculture (also referred to as "the Department") amends these provisions from time to time to incorporate new scientific information and technologies within the Plan. In addition, the regulations in 9 CFR part 56 set out conditions for the payment of indemnity for costs associated with poultry that are infected with or exposed to H5/H7 low pathogenic avian influenza and provisions for a cooperative control program for the disease.

On March 24, 2016, we published in the **Federal Register** (81 FR 15652–15660, Docket No. APHIS–2014–0101) a proposal[1] to amend the regulations by clarifying who may participate in the NPIP and amending participation requirements. In addition, we proposed to amend definitions of *poultry* and *breeding stock,* amend the approval process for new diagnostic tests, and amend slaughter plant inspection and laboratory inspection and testing requirements.

We solicited comments concerning our proposal for 60 days ending May 23, 2016. We received one comment by that date. It was from an individual. The issues raised by the commenter are discussed below.

In the March 2016 proposed rule, we proposed to amend the definition of *breeding flock* in § 56.1 to remove the word "chicks" and replace it with the word "progeny." The commenter objected to this change, suggesting that many people would not know the meaning of the latter term and would find it confusing.

We are not making any changes to the final rule in response to this comment. As stated in the March 2016 proposed rule, the term "progeny" is more accurate than "chicks" in this context because it is more inclusive of both chicken and turkey flocks. Young turkeys are known as poults rather than chicks. In addition, as we noted in the proposed rule, the change in terminology also makes our definition of *breeding flock* in § 56.1 consistent with our definition of *multiplier breeding flock* in § 145.1.

The March 2016 proposed rule included a minor change to § 145.12, which contains requirements for the retention and examination of records for all flocks maintained primarily for hatching eggs. We proposed to specify, in paragraph (b) of that section, that records for all breeder flock hatcheries must be made available for annual examination by a State inspector. Historically, testing records were retained at the hatchery, which allowed for examination of the records during annual inspections, but that is no longer the case. Many commercial hatcheries now keep testing records at the corporate office or another site. Our proposed amendment to § 145.12 was intended to reflect this change in recordkeeping practices in the industry and also to allow flexibility in the regulations regarding who may make the records available to the State inspector.

The commenter objected to this proposed change, stating that the records should be kept at the hatchery with the flocks so that taxpayers do not have to incur additional costs due to the need for inspectors to travel to different locations.

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[1] To view the proposed rule and the comment we received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0101.*

We do not agree with this comment. As noted above, we are amending the regulations to reflect current practices in the industry. By allowing hatcheries the discretion to maintain records where they would most readily be accessible when needed, we are relieving a regulatory burden. The commenter provides no evidence to support the claim that having the records kept at sites other than the hatcheries will result in additional costs to taxpayers.

The commenter also stated that the proposed rule would have the effect of loosening testing standards, thereby increasing the risk of the spread of disease.

We did not propose to loosen existing testing standards, as the commenter claims. We proposed instead to make some editorial changes to § 145.14(b) to remove references to tests that are no longer being used, update terminology that is no longer current, and otherwise clarify the testing requirements in that section.

Finally, the commenter objected to our proposed changes to the slaughter plant inspection requirements in § 146.11.

We will not be making any changes to the final rule in response to this comment. The commenter did not offer a rationale for opposing the proposed amendments to § 146.11, which were intended to clarify our slaughter plant inspection requirements and remove language that conflicted with requirements set out elsewhere in part 146.

Miscellaneous

In this final rule, we are making one minor editorial change to correct an error in the regulatory text of the proposed rule.

Part 146 of the regulations contains the NPIP provisions for commercial poultry. Currently, the only disease addressed in this part is H5/H7 low pathogenic avian influenza; under part 146, table-egg layer flocks, meat-type chicken slaughter plants, meat-type turkey slaughter plants, and certain types of game birds and waterfowl may participate in U.S. H5/H7 Avian Influenza Monitored classifications.

Section 146.11 sets out the audit process for participating slaughter plants. Paragraph (b) states that flocks slaughtered at a slaughter plant will be considered to be not conforming to the required protocol of the classifications if there are no test results available, if the flock was not tested within 21 days before slaughter, or if the test results for the flocks were not returned before slaughter. We intended to amend paragraph (b) to state that "a flock will be considered to be conforming to protocol if it meets the requirements as described in §§ 146.33(a), 146.43(a), 146.53(a)." However, we inadvertently referred to § 145.33(a) instead of § 146.33(a). In this final rule, we are correcting that error.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with the change discussed in this document.

Executive Order 12866 and Regulatory Flexibility Act

This final rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

In accordance with the Regulatory Flexibility Act, we have analyzed the potential economic effects of this action on small entities. The analysis is summarized below. Copies of the full analysis are available on the *Regulations.gov* Web site (see footnote 1 in this document for a link to Regulations.gov) or by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

We are amending the NPIP, its auxiliary provisions, and the indemnity regulations for the control of H5 and H7 low pathogenic avian influenza to align the regulations with international standards and make them more transparent to stakeholders and the general public. The changes in this final rule were voted on and approved by the voting delegates at the 2014 NPIP National Plan Conference.

The establishments that will be affected by the rule—principally entities engaged in poultry production and processing—are predominantly small by Small Business Administration standards. In those instances in which an addition to or modification of requirements could potentially result in a cost to certain entities, we do not expect the costs to be significant. NPIP membership is voluntary. The changes contained in this final rule were decided upon by the NPIP General Conference Committee on behalf of Plan members; that is, the changes were recognized by the poultry industry as being in their interest.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 2 CFR chapter IV.)

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are in conflict with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this final rule, which were filed under 0579–0445, have been submitted for approval to the Office of Management and Budget (OMB). When OMB notifies us of its decision, if approval is denied, we will publish a document in the **Federal Register** providing notice of what action we plan to take.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this rule, please contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2727.

List of Subjects

9 CFR Part 56

Animal diseases, Indemnity payments, Low pathogenic avian influenza, Poultry.

9 CFR Parts 145, 146, and 147

Animal diseases, Poultry and poultry products, Reporting and recordkeeping requirements.

Accordingly, we are amending 9 CFR parts 56, 145, 146, and 147 as follows:

PART 56—CONTROL OF H5/H7 LOW PATHOGENIC AVIAN INFLUENZA

■ 1. The authority citation for part 56 continues to read as follows:

Authority: 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

■ 2. Section 56.1 is amended by revising the definition of *breeding flock* to read as follows:

§ 56.1 Definitions.

* * * * *

Breeding flock. A flock that is composed of stock that has been developed for commercial egg or meat production and is maintained for the principal purpose of producing progeny for the ultimate production of eggs or meat for human consumption.

* * * * *

PART 145—NATIONAL POULTRY IMPROVEMENT PLAN FOR BREEDING POULTRY

■ 3. The authority citation for part 145 continues to read as follows:

Authority: 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

§ 145.2 [Amended]

■ 4. In § 145.2, paragraph (d) is amended by removing the reference "§ 145.3(d)" and adding the reference "§ 145.3(e)" in its place.

■ 5. Section 145.3 is amended as follows:

■ a. By redesignating paragraphs (a) through (f) as paragraphs (b) through (g), respectively.

■ b. By adding a new paragraph (a).

The addition reads as follows:

§ 145.3 Participation.

(a) The National Poultry Improvement Plan is a cooperative Federal-State-Industry program through which new or existing diagnostic technology can be effectively applied to improve poultry and poultry products by controlling or eliminating specific poultry diseases. The Plan consists of programs that identify States, flocks, hatcheries, dealers, and slaughter plants that meet specific disease control standards specified in the Plan. Participants shall maintain records to demonstrate that they adhere to the disease control programs in which they participate.

* * * * *

§ 145.12 [Amended]

■ 6. Section 145.12 is amended by adding, in paragraph (b), the words "made available to and" before the word "examined".

■ 7. Section 145.14 is amended as follows:

■ a. By revising paragraph (a)(5).

■ b. By revising paragraph (b)(1).

The revisions read as follows:

§ 145.14 Testing.

* * * * *

(a) * * *

(5) The official blood test shall include the testing of a sample of blood from each bird in the flock: Provided, That under specified conditions (see applicable provisions of §§ 145.23, 145.33, 145.43, 145.53, 145.63, 145.73, 145.83, and 145.93) the testing of a portion or sample of the birds may be used in lieu of testing each bird.

* * * * *

(b) * * *

(1) The official tests for *M. gallisepticum, M. meleagridis,* and *M. synoviae* shall be the serum plate agglutination test, the hemagglutination inhibition (HI) test, the enzyme-linked immunosorbent assay (ELISA) test,[3] or a molecular based test. The HI test or molecular based test shall be used to confirm the positive results of other serological screening tests. HI titers of 1:40 or more may be interpreted as suspicious, and final judgment must be based on further samplings and/or culture of reactors. Tests must be conducted in accordance with this paragraph (b) and in accordance with part 147 of this subchapter.

* * * * *

■ 8. In § 145.42, paragraph (b) is revised to read as follows:

§ 145.42 Participation.

* * * * *

(b) Hatching eggs should be nest clean. They may be fumigated in accordance with part 147 of this subchapter or otherwise sanitized.

* * * * *

■ 9. Section 145.53 is amended as follows:

■ a. By revising paragraphs (c)(1)(i), (c)(1)(ii) introductory text, and (c)(1)(ii)(A).

■ b. By revising paragraphs (d)(1)(i), (d)(1)(ii) introductory text, and (d)(1)(ii)(A).

The revisions read as follows:

§ 145.53 Terminology and classification; flocks and products.

* * * * *

(c) * * *

(1) * * *

(i) It is a flock in which all birds or a sample of at least 300 birds has been tested for *M. gallisepticum* as provided in § 145.14(b) when more than 4 months of age or upon reaching sexual maturity: *Provided,* That to retain this classification, a random sample of serum or egg yolk or a targeted bird sample of the choanal palatine cleft/fissure area using appropriate swabs from all the birds in the flock if the flock size is less than 30, but at least 30 birds, shall be tested at intervals of not more than 90 days: *And provided further,* That a sample comprised of less than 30 birds may be tested at any one time, with the approval of the Official State Agency and the concurrence of the Service, provided that a total of at least 30 birds, or all birds in the flock if flock size is less than 30, is tested within each 90-day period; or

(ii) It is a multiplier breeding flock which originated as U.S. M. Gallisepticum Clean baby poultry from primary breeding flocks and a random sample comprised of 50 percent of the birds in the flock, with a maximum of 200 birds and a minimum of 30 birds per flock or all birds in the flock if the flock size is less than 30 birds, has been tested for *M. gallisepticum* as provided in § 145.14(b) when more than 4 months of age or upon reaching sexual maturity: Provided, That to retain this classification, the flock shall be subjected to one of the following procedures:

(A) At intervals of not more than 90 days, a random sample of serum or egg yolk or a targeted bird sample of the choanal palatine cleft/fissure area using appropriate swabs from all the birds in the flock if flock size is less than 30, but at least 30 birds, shall be tested; or

* * * * *

(d) * * *

(1) * * *

(i) It is a flock in which all birds or a sample of at least 300 birds has been tested for *M. synoviae* as provided in § 145.14(b) when more than 4 months of age or upon reaching sexual maturity: *Provided,* That to retain this classification, a random sample of serum or egg yolk or a targeted bird sample of the choanal palatine cleft/fissure area using appropriate swabs (C.P. swabs) from all the birds in the flock if flock size is less than 30, but at least 30 birds, shall be tested at intervals of not more than 90 days: *And provided further,* That a sample comprised of less than 30 birds may be tested at any one time with the approval of the Official State Agency and the concurrence of the Service, provided that a total of at least 30 birds is tested within each 90-day period; or

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[3] Procedures for the enzyme-linked immunosorbent assay (ELISA) test are set forth in the following publications:

A.A. Ansari, R.F. Taylor, T.S. Chang, "Application of Enzyme-Linked Immunosorbent Assay for Detecting Antibody to Mycoplasma gallisepticum Infections in Poultry," *Avian Diseases,* Vol. 27, No. 1, pp. 21–35, January-March 1983; and

H.M. Opitz, J.B. Duplessis, and M.J. Cyr, "Indirect Micro-Enzyme-Linked Immunosorbent Assay for the Detection of Antibodies to Mycoplasma synoviae and M. gallisepticum," *Avian Diseases,* Vol. 27, No. 3, pp. 773–786, July-September 1983; and

H.B. Ortmayer and R. Yamamoto, "Mycoplasma Meleagridis Antibody Detection by Enzyme-Linked Immunosorbent Assay (ELISA)," *Proceedings, 30th Western Poultry Disease Conference,* pp. 63–66, March 1981.

(ii) It is a multiplier breeding flock that originated as U.S. M. Synoviae Clean chicks from primary breeding flocks and from which a random sample comprised of 50 percent of the birds in the flock, with a maximum of 200 birds and a minimum of 30 birds per flock or all birds in the flock if the flock is less than 30 birds, has been tested for *M. synoviae* as provided in § 145.14(b) when more than 4 months of age or upon reaching sexual maturity: *Provided,* That to retain this classification, the flock shall be subjected to one of the following procedures:

(A) At intervals of not more than 90 days, a random sample of serum or egg yolk or a targeted bird sample of the choanal palantine cleft/fissure area using appropriate swabs from all the birds in the flock if the flock size is less than 30, but at least 30 birds shall be tested: *Provided,* That a sample of fewer than 30 birds may be tested at any one time with the approval of the Official State Agency and the concurrence of the Service, provided that a total of at least 30 birds, or the entire flock if flock size is less than 30, is tested each time and a total of at least 30 birds is tested within each 90-day period; or

* * * * *

■ 10. Section 145.83 is amended as follows:

■ a. By revising paragraph (f)(1)(i).

■ b. By removing paragraphs (f)(1)(ii) and (f)(1)(iii).

■ c. By redesignating paragraphs (f)(1)(iv) through (f)(1)(viii) as paragraphs (f)(1)(ii) through (f)(1)(vi).

■ d. In newly redesignated paragraphs (f)(1)(v) and (f)(1)(vi) by removing the words "(f)(1)(vi)" and adding the words "(f)(1)(iv)" in their place.

■ e. By revising paragraph (f)(3).

The revisions read as follows:

§ 145.83 Terminology and classification; flocks and products.

* * * * *

(f) * * *

(1) * * *

(i) Measures shall be implemented to control *Salmonella* challenge through feed, feed storage, and feed transport.

* * * * *

(3) In order for a hatchery to sell products of paragraphs (f)(1)(i) through (f)(1)(vi) of this section, all products handled shall meet the requirements of the classification.

* * * * *

■ 11. In § 145.92, paragraph (b) is revised to read as follows:

§ 145.92 Participation.

* * * * *

(b) Hatching eggs produced by primary and multiplier breeding flocks should be nest clean. They may be fumigated in accordance with part 147 of this subchapter or otherwise sanitized.

* * * * *

§ 145.93 [Amended]

■ 12. In § 145.93, paragraph (c)(3) is amended by removing the number "30" and adding the number "11" in its place.

PART 146—NATIONAL POULTRY IMPROVEMENT PLAN FOR COMMERCIAL POULTRY

■ 13. The authority citation for part 146 continues to read as follows:

Authority: 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

■ 14. Section 146.1 is amended by revising the definition of *poultry* to read as follows:

§ 146.1 Definitions.

* * * * *

Poultry. Domesticated fowl, including chickens, turkeys, waterfowl, and game birds, except doves and pigeons, that are bred for the primary purpose of producing eggs or meat.

* * * * *

■ 15. Section 146.2 is amended by revising paragraph (c) to read as follows:

§ 146.2 Administration.

* * * * *

(c)(1) An Official State Agency may accept for participation a commercial table-egg layer pullet flock, commercial table-egg layer flock, or a commercial meat-type flock (including an affiliated flock) located in another participating State under a mutual understanding and agreement, in writing, between the two Official State Agencies regarding conditions of participation and supervision.

(2) An Official State Agency may accept for participation a commercial table-egg layer pullet flock, commercial table-egg layer flock, or a commercial meat-type flock (including an affiliated flock) located in a State that does not participate in the Plan under a mutual understanding and agreement, in writing, between the owner of the flock and the Official State Agency regarding conditions of participation and supervision.

* * * * *

§ 146.3 [Amended]

■ 16. In § 146.3, paragraph (a) is amended by adding the words "commercial table-egg layer pullet flock," before the words "table-egg producer".

■ 17. In § 146.11, paragraph (b) is revised to read as follows:

§ 146.11 Inspections.

* * * * *

(b) A flock will be considered to be conforming to protocol if it meets the requirements as described in § 146.33(a), § 146.43(a), or § 146.53(a).

* * * * *

§ 146.51 [Amended]

■ 18. Section 146.51 is amended as follows:

■ a. In the definition of *commercial upland game birds* by removing the word "purpose" and adding in its place "purposes" and adding the words "eggs and/or" before the word "meat".

■ b. In the definition of *commercial waterfowl,* by removing the word "purpose" and adding in its place "purposes" and adding the words "eggs and/or" before the word "meat".

■ 19. Section 146.52 is amended by revising paragraphs (a) and (c) to read as follows:

§ 146.52 Participation.

(a) Participating commercial upland game bird slaughter plants, commercial waterfowl slaughter plants, raised-for-release upland game bird premises, raised-for-release waterfowl premises, and commercial upland game bird and commercial waterfowl producing eggs for human consumption premises shall comply with the applicable general provisions of subpart A of this part and the special provisions of this subpart E.

* * * * *

(c) Raised-for-release upland game bird premises, raised-for-release waterfowl premises, and commercial upland game bird and commercial waterfowl producing eggs for human consumption premises that raise fewer than 25,000 birds annually are exempt from the special provisions of this subpart E.

■ 20. Section 146.53 is amended as follows:

■ a. In paragraph (a) introductory text, by adding the words "or, in the case of egg-producing flocks, the regular surveillance of these flocks" after the words "participating slaughter plant".

■ b. By adding paragraphs (a)(4) and (a)(5).

The additions read as follows:

§ 146.53 Terminology and classification; slaughter plants and premises.

* * * * *

(a) * * *

(4) It is a commercial upland game bird or waterfowl flock that produces eggs for human consumption where a minimum of 11 birds per flock have been tested negative to the H5/H7 subtypes of avian influenza as provided in § 146.13(b) within 30 days of disposal or within a 12 month period.

(5) It is a commercial upland game bird or waterfowl flock that has an on-going active and passive surveillance program for H5/H7 subtypes of avian influenza that is approved by the Official State Agency and the Service.

* * * * *

PART 147—AUXILIARY PROVISIONS ON NATIONAL POULTRY IMPROVEMENT PLAN

■ 21. The authority citation for part 147 continues to read as follows:

Authority: 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

■ 22. In § 147.52, paragraph (d) is revised to read as follows:

§ 147.52 Authorized laboratories.

* * * * *

(d) *State site visit.* The Official State Agency will conduct a site visit and recordkeeping audit at least once every 2 years. This will include, but may not be limited to, review of technician training records, check test proficiency, and test results. The information from the site visit and recordkeeping audit will be made available to the NPIP upon request.

* * * * *

■ 23. Section 147.54 is revised to read as follows:

§ 147.54 Approval of diagnostic test kits not licensed by the Service.

(a) Diagnostic test kits that are not licensed by the Service (*e.g.,* bacteriological culturing kits) may be approved through the following procedure:

(1) The sensitivity of the kit will be evaluated in at least three NPIP authorized laboratories by testing known positive samples, as determined by the official NPIP procedures found in the NPIP Program Standards or through other procedures approved by the Administrator. Field samples for which the presence or absence of the target organism or analyte has been determined by the current NPIP test should be used, not spiked samples or pure cultures. Samples from a variety of field cases representing a range of low, medium, and high analyte concentrations should be used. In some cases it may be necessary to utilize samples from experimentally infected animals. Spiked samples (clinical sample matrix with a known amount of pure culture added) should only be used in the event that no other sample types are available. Pure cultures should never be used. Additionally, laboratories should be selected for their experience with testing for the target organism or analyte with the current NPIP approved test. If certain conditions or interfering substances are known to affect the performance of the kit, appropriate samples will be included so that the magnitude and significance of the effect(s) can be evaluated.

(2) The specificity of the kit will be evaluated in at least three NPIP authorized laboratories by testing known negative samples, as determined by tests conducted in accordance with the NPIP Program Standards or other procedures approved by the Administrator in accordance with § 147.53(d)(1). If certain conditions or interfering substances are known to affect the performance of the kit, appropriate samples will be included so that the magnitude and significance of the effect(s) can be evaluated.

(3) The kit will be provided to the cooperating laboratories in its final form and include the instructions for use. The cooperating laboratories must perform the assay exactly as stated in the supplied instructions. Each laboratory must test a panel of at least 25 known positive samples. In addition, each laboratory will be asked to test at least 50 known negative samples obtained from several sources, to provide a representative sampling of the general population. The cooperating laboratories must perform a current NPIP procedure or NPIP approved test on the samples alongside the test kit for comparison.

(4) Cooperating laboratories will submit to the kit manufacturer all raw data regarding the assay response. Each sample tested will be reported as positive or negative, and the official NPIP procedure used to classify the sample must be submitted in addition to the assay response value. A completed worksheet for diagnostic test evaluation is required to be submitted with the raw data and may be obtained by contacting the NPIP Senior Coordinator. Raw data and the completed worksheet for diagnostic test evaluation must be submitted to the NPIP Senior Coordinator 4 months prior to the next scheduled General Conference Committee meeting, which is when approval will be sought.

(5) The findings of the cooperating laboratories will be evaluated by the NPIP Technical Committee, and the Technical Committee will make a majority recommendation whether to approve the test kit to the General Conference Committee at the next scheduled General Conference Committee meeting. If the Technical Committee recommends approval, the final approval will be granted in accordance with the procedures described in §§ 147.46, 147.47, and 147.48.

(6) Diagnostic test kits that are not licensed by the Service (*e.g.,* bacteriological culturing kits) and that have been approved for use in the NPIP in accordance with this section are listed in the NPIP Program Standards.

(b) *Approved tests modification and removal.* (1) The specific data required for modifications of previously approved tests will be taken on a case-by-case basis by the technical committee.

(2) If the Technical Committee determines that only additional field data is needed at the time of submission for a modification of a previously approved test, allow for a conditional approval for 60 days for data collection side-by-side with a current test. The submitting party must provide complete protocol and study design, including criteria for pass/fail to the Technical Committee. The Technical Committee must review the data prior to final approval. This would only apply to the specific situation where a modified test needs additional field data with poultry to be approved.

(3) Approved diagnostic tests may be removed from the Plan by submission of a proposed change from a participant, Official State Agency, the Department, or other interested person or industry organization. The data in support of removing an approved test will be compiled and evaluated by the NPIP Technical Committee, and the Technical Committee will make a majority recommendation whether to remove the test kit to the General Conference Committee at the next scheduled General Conference Committee meeting. If the Technical Committee recommends removal, the final decision to remove the test will be granted in accordance with the procedures described in §§ 147.46, 147.47, and 147.48.

Done in Washington, DC, this 9th day of August 2016.

Jere L. Dick,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2016–19245 Filed 8–11–16; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–5465; Directorate Identifier 2015–NM–041–AD; Amendment 39–18609; AD 2016–16–11]

RIN 2120–AA64

Airworthiness Directives; BAE Systems (Operations) Limited Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are superseding Airworthiness Directive (AD) 2010–10–13, for all BAE Systems (Operations) Limited Model BAe 146 and Avro 146 series airplanes. AD 2010–10–13 required repetitive inspections of the wing fixed leading edge and front spar structure for corrosion and cracking, and repair if necessary. This new AD requires revised inspection procedures that terminate a previously approved inspection procedure. This AD was prompted by revised inspection procedures issued by the Design Approval Holder (DAH). We are issuing this AD to detect and correct corrosion and cracking of the wing fixed leading edge and front spar structure, which could result in reduced structural integrity of the airplane.

DATES: This AD is effective September 16, 2016.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of September 16, 2016.

The Director of the Federal Register approved the incorporation by reference of a certain other publication listed in this AD as of June 21, 2010 (75 FR 27419, May 17, 2010).

ADDRESSES: For service information identified in this final rule, contact BAE Systems (Operations) Limited, Customer Information Department, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland, United Kingdom; telephone +44 1292 675207; fax +44 1292 675704; email *RApublications@baesystems.com;* Internet *http://www.baesystems.com/Businesses/RegionalAircraft/index.htm.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–5465.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–5465; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (telephone 800–647–5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Todd Thompson, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1175; fax 425–227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2010–10–13, Amendment 39–16292 (75 FR 27419, May 17, 2010) (''AD 2010–10–13''). AD 2010–10–13 applied to all BAE Systems (Operations) Limited Model BAe 146 and Avro 146 series airplanes. The NPRM published in the **Federal Register** on April 20, 2016 (81 FR 23208) (''the NPRM''). The NPRM was prompted by revised inspection procedures issued by the DAH. The NPRM proposed to continue to require repetitive inspections of the wing fixed leading edge and front spar structure for corrosion and cracking, and repair if necessary. The NPRM also proposed to require revised inspection procedures that terminate a previously approved inspection procedure. We are issuing this AD to detect and correct corrosion and cracking of the wing fixed leading edge and front spar structure, which could result in reduced structural integrity of the airplane.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2014–0047; corrected February 26, 2015 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''); to correct an unsafe condition. The MCAI states:

> Corrosion of the wing fixed leading edge structure was detected on a BAe 146 aeroplane during removal of wing removable edge for a repair. The review of available scheduled tasks intended to detect environmental and fatigue deteriorations of the wing revealed that they may not have been sufficient to identify corrosion or fatigue damage in the affected structural area.
>
> This condition, if not detected and corrected, could lead to degradation of the structural integrity of the wing.
>
> To address this potential unsafe condition, EASA issued AD 2009–0014 [which corresponds to FAA AD 2010–10–13] to require repetitive inspections of fixed wing leading edge and front spar structure [for cracking and corrosion, and repair if necessary] in accordance with BAE Systems (Operations) Ltd Inspection Service Bulletin (ISB) ISB.57–072 which incorporated two possible inspection procedures, either method 1, a combination of a detailed visual inspection (DVI) and a visual inspection (VI) after removal of the outer fixed leading edge only, or method 2, a DVI only, after removal of the inner, centre and outer fixed leading edges.
>
> Since that [EASA] AD was issued, BAE Systems (Operations) Ltd issued ISB.57–072 Revision 1 to correct a material reference number, Revision 2, which removed method 1 as an available inspection procedure to detect fatigue and environmental damage of the wing structure and Revision 3 to delete the requirement to install weights if the engines were removed when the leading edges were removed.
>
> For the reasons described above, this [EASA] AD retains the requirements of EASA AD 2009–0014, which is superseded, but requires accomplishment of the [repetitive] inspections in accordance with updated inspection procedures, *i.e.* method 2 only.
>
> This [EASA] AD is re-published to correct a typographical error in Table 1, restoring a compliance time as previously required by EASA AD 2009–0014.

The repetitive inspection interval for the detailed visual inspection for cracking and corrosion of the wing fixed leading edge and front spar structure is:

- 12 years or 36,000 flight cycles, whichever occurs earlier, for airplanes on which the enhanced corrosion protection has not been accomplished.
- 6 years or 36,000 flight cycles, whichever occurs earlier, for airplanes on which the enhanced corrosion protection has been accomplished.

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–5465.

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

We reviewed the available data and determined that air safety and the public interest require adopting this AD as proposed except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

BAE Systems (Operations) Limited has issued Service Bulletin ISB.57–072, Revision 3, dated August 31, 2010. The service information describes procedures for inspection and repair for cracking and corrosion of the wing fixed leading edge and front spar structure. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

We estimate that this AD affects 4 airplanes of U.S. registry.

The actions required by AD 2010–10–13, and retained in this AD take about 12 work-hours per product, and 1 work-hour per product for reporting, at an average labor rate of $85 per work-hour. Based on these figures, the estimated cost of the actions that are required by AD 2010–10–13 is $1,105 per product.

The new requirements of this AD add no additional economic burden.

We have received no definitive data that would enable us to provide cost estimates for the on-condition actions specified in this AD.

Paperwork Reduction Act

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB control number. The control number for the collection of information required by this AD is 2120–0056. The paperwork cost associated with this AD has been detailed in the Costs of Compliance section of this document and includes time for reviewing instructions, as well as completing and reviewing the collection of information. Therefore, all reporting associated with this AD is mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at 800 Independence Ave. SW., Washington, DC 20591, ATTN: Information Collection Clearance Officer, AES–200.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2010–10–13, Amendment 39–16292 (75 FR 27419, May 17, 2010), and adding the following new AD:

2016–16–11 BAE Systems (Operations) Limited: Amendment 39–18609. Docket No. FAA–2016–5465; Directorate Identifier 2015–NM–041–AD.

(a) Effective Date

This AD is effective September 16, 2016.

(b) Affected ADs

This AD replaces AD 2010–10–13, Amendment 39–16292 (75 FR 27419, May 17, 2010) ("AD 2010–10–13").

(c) Applicability

This AD applies to BAE Systems (Operations) Limited Model BAe 146–100A, –200A, and –300A series airplanes; and Model Avro 146–RJ70A, 146–RJ85A, and 146–RJ100A airplanes; certificated in any category, all serial numbers.

(d) Subject

Air Transport Association (ATA) of America Code 57, Wings.

(e) Reason

This AD was prompted by revised inspection procedures issued by the Design Approval Holder. We are issuing this AD to detect and correct corrosion and cracking of the wing fixed leading edge and front spar structure, which could result in reduced structural integrity of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Retained Actions and Compliance, With Added Provision for Terminating Action

This paragraph restates the requirements of paragraph (f) of AD 2010–10–13, with an added provision for terminating action. Accomplishing the initial inspection required by paragraph (j) of this AD terminates the requirements of paragraph (g) of this AD.

(1) At the applicable time identified in paragraph (g)(1)(i), (g)(1)(ii), or (g)(1)(iii) of this AD: Perform a detailed visual inspection and visual inspection (Method 1) or a detailed visual inspection (Method 2) for cracking and corrosion of the wing fixed leading edge and front spar structure, in

accordance with paragraph 2.C. or 2.D., as applicable, of the Accomplishment Instructions of BAE Systems (Operations) Limited Inspection Service Bulletin ISB.57–072, Revision 1, dated September 25, 2008.

(i) For airplanes with less than 9 years since the date of issuance of the original airworthiness certificate or the date of issuance of the original export certificate of airworthiness as of the effective date of this AD: Within 18 months after June 21, 2010 (the effective date of AD 2010–10–13).

(ii) For airplanes with 9 years or more, but less than 15 years, since the date of issuance of the original airworthiness certificate or the date of issuance of the original export certificate of airworthiness as of June 21, 2010 (the effective date of AD 2010–10–13): Within 18 months after June 21, 2010, or within 16 years since the date of issuance of the original airworthiness certificate or the date of issuance of the original export certificate of airworthiness, whichever occurs first.

(iii) For airplanes with 15 years or more since the date of issuance of the original airworthiness certificate or the date of issuance of the original export certificate of airworthiness as of June 21, 2010 (the effective date of AD 2010–10–13): Within 6 months after June 21, 2010.

(2) After doing the initial inspection required by paragraph (g)(1) of this AD, at the applicable intervals specified in paragraph (g)(2)(i) or (g)(2)(ii) of this AD, accomplish the repetitive inspections of the wing fixed leading edge and front spar structure for cracking and corrosion in the "area of inspection" specified in table 1 of paragraph 1.D., "Compliance," of BAE Systems (Operations) Limited Inspection Service Bulletin ISB.57–072, Revision 1, dated September 25, 2008. Do the inspections in accordance with paragraph 2.C. (Method 1) or paragraph 2.D. (Method 2) of the Accomplishment Instructions of BAE SYSTEMS (Operations) Limited Inspection Service Bulletin ISB.57–072, Revision 1, dated September 25, 2008. Where previously applied, enhanced corrosion protection may then be re-applied, as an option, in accordance with paragraph 2.E. of the Accomplishment Instructions of BAE Systems (Operations) Limited Inspection Service Bulletin ISB.57–072, Revision 1, dated September 25, 2008. Perform the repetitive inspections at the times specified in paragraph (g)(2)(i) or (g)(2)(ii) of this AD, as applicable.

(i) For airplanes having enhanced corrosion protection that was applied during the previous inspection: Inspect at intervals not to exceed 144 months.

(ii) For airplanes not having enhanced corrosion protection that was applied during the previous inspection: Inspect at intervals not to exceed 72 months.

(3) After doing the initial inspection required by paragraph (g)(1) of this AD, at intervals not to exceed 36,000 flight cycles, accomplish fatigue inspections in accordance with paragraph 2.C. (Method 1) or paragraph 2.D. (Method 2) of the Accomplishment Instructions of BAE Systems (Operations) Limited Inspection Service Bulletin ISB.57–072, Revision 1, dated September 25, 2008.

(4) If any cracking or corrosion is found during any inspection required by paragraph (g) of this AD, before further flight, repair in accordance with the Accomplishment Instructions of BAE Systems (Operations) Limited Inspection Service Bulletin ISB.57–072, Revision 1, dated September 25, 2008.

(5) No repair terminates the inspection requirements of this AD.

(6) Actions done before June 21, 2010 (the effective date of AD 2010–10–13), in accordance with BAE Systems (Operations) Limited Inspection Service Bulletin ISB.57–072, dated February 22, 2008, are considered acceptable for compliance with the corresponding actions specified in this AD.

(7) Submit a report of the findings (both positive and negative) of the inspection required by paragraph (f)(1) of this AD to Customer Liaison, Customer Support (Building 37), BAE Systems (Operations) Limited, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland; fax +44 (0) 1292 675432; email *raengliaison@baesystems.com,* at the applicable time specified in paragraphs (g)(7)(i) and (g)(7)(ii) of this AD. The report must include the inspection results, a description of any discrepancies found, the airplane serial number, and the number of landings and flight hours on the airplane.

(i) If the inspection was done on or after June 21, 2010 (the effective date of AD 2010–10–13): Submit the report within 30 days after the inspection.

(ii) If the inspection was done before June 21, 2010 (the effective date of AD 2010–10–13): Submit the report within 30 days after June 21, 2010.

(h) Retained Corrosion Protection Information, With No Changes

This paragraph restates the corrosion protection information in Note 2 of AD 2010–10–13, with no changes. At the discretion of the airplane owner/operator, corrosion protection may be embodied on those areas subject to a detailed visual inspection, in accordance with paragraph 2.E. or paragraph 2.F. of the Accomplishment Instructions of BAE Systems (Operations) Limited Inspection Service Bulletin ISB.57–072, Revision 1, dated September 25, 2008. Embodiment of enhanced corrosion protection in accordance with paragraph 2.E. of the Accomplishment Instructions of BAE Systems (Operations) Limited Inspection Service Bulletin ISB.57–072, Revision 1, dated September 25, 2008, allows the interval of the repetitive inspections (as required by paragraph (g)(2) of this AD) to be extended in the area(s) of application in accordance with paragraph (g)(2)(i) or (g)(2)(ii) of this AD, as applicable.

(i) Retained Inspection Information, With No Changes

This paragraph restates the inspection information in Note 3 of AD 2010–10–13, with no changes. The inspections required by this AD prevail over the Maintenance Review Board Report (MRBR), Maintenance Planning Document (MPD), Corrosion Prevention and Control Program (CPCP), and Supplemental Structural Inspection Document (SSID) inspections defined in paragraph 1.C.(3) of BAE Systems (Operations) Limited Inspection Service Bulletin ISB.57–072, Revision 1, dated September 25, 2008.

(j) New Requirement of This AD: Repetitive Inspection

At the applicable time identified in paragraph (j)(1), (j)(2), or (j)(3) of this AD; or within 6 months after the effective date of this AD; whichever occurs later: Perform a detailed visual inspection for cracking and corrosion of the wing fixed leading edge and front spar structure, in accordance with paragraph 2.C. of the Accomplishment Instructions of BAE Systems (Operations) Limited Inspection Service Bulletin ISB.57–072, Revision 3, dated August 31, 2010. Repeat the inspection thereafter at the applicable intervals specified in paragraph 1.D.2. of BAE Systems (Operations) Limited Inspection Service Bulletin ISB.57–072, Revision 3, dated August 31, 2010. Accomplishing the initial inspection required by this paragraph terminates the requirements of paragraph (g) of this AD.

(1) For airplanes with less than 9 years since the date of issuance of the original airworthiness certificate or the date of issuance of the original export certificate of airworthiness as of June 21, 2010 (the effective date of AD 2010–10–13): Within 18 months after June 21, 2010, or within 9 years since the date of issuance of the original airworthiness certificate or the date of issuance of the original export certificate of airworthiness, whichever occurs later.

(2) For airplanes with 9 years or more, but less than 15 years, since the date of issuance of the original airworthiness certificate or the date of issuance of the original export certificate of airworthiness as of June 21, 2010 (the effective date of AD 2010–10–13): Within 18 months after June 21, 2010, or within 16 years since the date of issuance of the original airworthiness certificate or the date of issuance of the original export certificate of airworthiness, whichever occurs first.

(3) For airplanes with 15 years or more since the date of issuance of the original airworthiness certificate or the date of issuance of the original export certificate of airworthiness as of June 21, 2010 (the effective date of AD 2010–10–13): Within 6 months after June 21, 2010.

(k) New Requirement of This AD: Repair

If any crack or corrosion is found during any inspection required by paragraph (j) of this AD: Before further flight, repair using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or BAE Systems (Operations) Limited's EASA Design Organization Approval (DOA).

(l) No Provisions for Terminating Action

Accomplishment of any repair, as required by paragraph (k) of this AD, does not constitute terminating action for inspections required by this AD.

(m) Credit for Previous Actions

This paragraph provides credit for actions required by this AD, if those actions were performed before the effective date of this AD using BAE Systems (Operations) Limited Inspection Service Bulletin ISB.57–072, dated February 22, 2008; or BAE Systems (Operations) Limited Inspection Service Bulletin ISB.57–072, Revision 1, dated September 25, 2008.

(n) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Todd Thompson, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1175; fax 425–227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* As of the effective date of this AD, for any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the EASA; or BAE Systems (Operations) Limited's EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Reporting Requirements:* A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES–200.

(o) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2014–004; corrected February 26, 2015; for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–5465.

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (p)(5) and (p)(6) of this AD.

(p) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(3) The following service information was approved for IBR on September 16, 2016.

(i) BAE Systems (Operations) Limited Inspection Service Bulletin ISB.57–072, Revision 3, dated August 31, 2010.

(ii) Reserved.

(4) The following service information was approved for IBR on June 21, 2010 (75 FR 27419, May 17, 2010).

(i) BAE Systems (Operations) Limited Inspection Service Bulletin ISB.57–072, Revision 1, dated September 25, 2008.

(ii) Reserved.

(5) For service information identified in this AD, contact BAE Systems (Operations) Limited, Customer Information Department, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland, United Kingdom; telephone +44 1292 675207; fax +44 1292 675704; email *RApublications@baesystems.com;* Internet *http://www.baesystems.com/Businesses/RegionalAircraft/index.htm.*

(6) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(7) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on July 27, 2016.

Victor Wicklund,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–18821 Filed 8–11–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–3989; Directorate Identifier 2014–NM–250–AD; Amendment 39–18600; AD 2016–16–02]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for all Airbus Model A318, A319, A320, and A321 series airplanes. This AD was prompted by reports of premature aging of certain passenger chemical oxygen generators that resulted in the generators failing to activate. This AD requires an inspection to determine if certain passenger chemical oxygen generators are installed and replacement of affected passenger chemical oxygen generators. We are issuing this AD to prevent failure of the passenger chemical oxygen generator to activate and consequently not deliver oxygen during an emergency, possibly resulting in injury to the airplane occupants.

DATES: This AD is effective September 16, 2016.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of September 16, 2016.

ADDRESSES: For Airbus service information identified in this final rule, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone: +33 5 61 93 36 96; fax: +33 5 61 93 44 51; email: *account.airworth-eas@airbus.com;* Internet: *http://www.airbus.com.* For B/E Aerospace service information identified in this final rule, contact B/E Aerospace Inc., 10800 Pflumm Road, Lenexa, KS 66215; telephone: 913–338–9800; fax: 913–469–8419; Internet: *http://beaerospace.com/home/globalsupport.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–3989.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–3989; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone: 800–647–5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Sanjay Ralhan, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone: 425–227–1405; fax: 425–227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Airbus Model A318, A319, A320, and A321 series airplanes. The NPRM published in the **Federal Register** on October 19, 2015 (80 FR 63136) (“the NPRM”). The NPRM was prompted by reports of premature aging of certain passenger chemical oxygen generators that resulted in the generators failing to activate. The NPRM proposed to require an inspection to determine if certain passenger chemical oxygen generators are installed and replacement of affected passenger chemical oxygen generators. We are issuing this AD to prevent failure of the passenger chemical oxygen generator to activate and consequently not deliver oxygen during an emergency, possibly resulting in injury to the airplane occupants.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2015–0117, dated June 24, 2015; corrected August 7, 2015 (referred to after this as the Mandatory Continuing Airworthiness Information, or “the MCAI”); to correct an unsafe condition for all Airbus Model A318, A319, A320, and A321 series airplanes. The MCAI states:

> Reports have been received indicating premature ageing of certain chemical oxygen generators, Part Number (P/N) 117042–XX (XX representing any numerical value), manufactured by B/E Aerospace. Some operators reported that when they tried to activate generators, some older units failed to activate. Given the number of failed units reported, all generators manufactured in 1999, 2000 and 2001 were considered unreliable.
>
> This condition, if not corrected, could lead to failure of the generator to activate and consequently not deliver oxygen during an emergency, possibly resulting in injury to aeroplane occupants.
>
> To address this potential unsafe condition, Airbus issued Alert Operators Transmission (AOT) A35N006–14, making reference to B/E Aerospace Service Information Letter (SIL) D1019–01 (currently at Revision 1) and B/E Aerospace Service Bulletin (SB) 117042–35–001.
>
> Consequently, EASA issued AD * * * (later revised) to require identification and replacement of the affected oxygen generators.
>
> Since EASA AD 2014–0275R1 was issued, and following new investigation results, EASA have decided to introduce a life limitation concerning all P/N 117042–XX chemical oxygen generators, manufactured by B/E Aerospace.
>
> For the reason described above, this [EASA] AD retains the requirements of the EASA AD 2014–0275R1, which is superseded, expands the scope of the [EASA] AD to include chemical oxygen generators manufactured after 2001, and requires their removal from service before exceeding 10 years since date of manufacture.
>
> This [EASA] AD is re-published to correct a template error, removing the word ‘Proposed’ and replacing the acronym ‘PAD’ with ‘AD’.

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–3989.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the NPRM (80 FR 63136, October 19, 2015) and the FAA’s response to each comment.

Requests To Extend Compliance Times

United Airlines (UAL) and Delta Air Lines, Inc. (DAL) requested an extension of the 30-day compliance time for the part number inspection. UAL stated that the time required for the part number inspection and the size of UAL’s fleet is prohibitive to meeting the 30-day compliance time and requested that we extend the initial compliance time to 24 months. DAL stated that the time required for the part number inspection and the size of DAL’s fleet is prohibitive to meeting the 30-day compliance time and requested that we extend the initial compliance time for the part number inspection to 90 days. DAL pointed out that a 90-day compliance time would allow ample time to route airplanes and schedule the required work on the first group of affected airplanes.

We disagree with the requests to extend the 30-day compliance time for the part number inspection. The commenters did not provide any justification to substantiate how increasing the compliance time from 30 days to 90 days or 24 months would provide an acceptable level of safety. After considering all of the available information, we have determined that the compliance time, as proposed, represents an appropriate interval of time in which the required actions can be performed in a timely manner with the affected fleet, while still maintaining an adequate level of safety. In developing an appropriated compliance time, we considered the safety implications, parts availability, and normal maintenance schedules for timely accomplishment of the replacement, overall risk to the fleet, including the severity of the identified unsafe condition and the likelihood of the occurrence of the unsafe condition. However, under the provisions of paragraph (n)(1) of this AD, operators may apply for an extension of the compliance time by providing rationale explaining why a compliance time extension provides an acceptable level of safety. We have not changed this AD in this regard.

Request To Revise Cost Estimates

DAL requested that we revise the Costs of Compliance section provided in the NPRM. DAL pointed out that the cost estimate may not properly account for the number of products per airplane and that they believe the costs are significantly higher than the estimate included in the NPRM. DAL also provided revised cost estimates based on their fleet.

We partially agree with the request to revise the Costs of Compliance section. We disagree that the cost estimate should be revised based on airplane configuration, findings, and associated costs based only on the DAL fleet. The configuration of each airplane and inspection findings may vary among U.S. operators. We agree that the Costs of Compliance section provided in the NPRM might not have accurately represented the actual cost. After considering the data presented by DAL, we also agree that the number of work-hours required is higher than our previous estimate. The Costs of Compliance section of this final rule has been revised accordingly.

Request To Remove Reporting Requirement

UAL requested that we remove the reporting requirement in the proposed AD. UAL pointed out that reporting could expose operators to compliance risk. UAL also pointed out that they do not find any value in the information being requested by the reporting requirement. UAL stated that they will provide any feedback as requested.

We disagree with the request to remove the reporting requirement. We disagree that the information requested provides no value. Reporting is necessary for the airframe manufacturer to determine the extent of the unsafe condition and any necessary follow-up actions. We have not changed this AD in this regard.

Request To Reference Revised Service Information

Mr. Ricardo Erazo requested that we revise the AD to reference B/E Aerospace Service Bulletin 117042–35–001, Revision 004, dated October 13, 2015. Mr. Erazo did not provide rationale for this request.

We agree with the request to revise this AD to reference B/E Aerospace Service Bulletin 117042–35–001, Revision 004, dated October 13, 2015, and have revised this AD accordingly. B/E Aerospace Service Bulletin 117042–35–001, Revision 004, dated October 13, 2015, clarifies references to additional service information. As a result, we have also added paragraph (m) to this AD, to give credit for actions accomplished before the effective date of this AD using B/E Aerospace Service Bulletin 117042–35–001, dated December 10, 2014; B/E Aerospace Service Bulletin 117042–35–001, Revision 001, dated April 9, 2015; B/E Aerospace Service Bulletin 117042–35–001, Revision 002, dated May 29, 2015; or B/E Aerospace Service Bulletin 117042–35–001, Revision 003, dated June 25, 2015.

Change to Service Information References

We have revised paragraphs (h) and (i) of this AD to refer to Airbus AOT A35N006–14, dated December 10, 2014, including Appendix 1, as an additional appropriate source of service information for the 15-minute passenger chemical oxygen generators.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this AD with the changes described previously and minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this AD.

Related Service Information Under 1 CFR Part 51

We reviewed the following service information.

- Airbus AOT A35N006–14, dated December 10, 2014, including Appendix 1.
- B/E Aerospace Inc. Service Bulletin 117042–35–001, Revision 004, dated October 13, 2015.

This service information describes procedures to replace certain passenger chemical oxygen generators. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

We estimate that this AD affects 953 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Part number inspection	4 work-hours × $85 per hour = $340	$0	$340	$324,020
Reporting	1 work-hour × $85 per hour = $85	0	85	81,005

We estimate the following costs to do any necessary replacements that would be required based on the results of the required inspection. We have no way of determining the number of airplanes that might need these replacements:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replacement	Up to 25 work-hours × $85 per hour = $2,125	$390	Up to $2,515.

Paperwork Reduction Act

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB control number. The control number for the collection of information required by this AD is 2120–0056. The paperwork cost associated with this AD has been detailed in the Costs of Compliance section of this document and includes time for reviewing instructions, as well as completing and reviewing the collection of information. Therefore, all reporting associated with this AD is mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at 800 Independence Ave. SW., Washington, DC 20591, ATTN: Information Collection Clearance Officer, AES–200.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2016–16–02 Airbus: Amendment 39–18600. Docket No. FAA–2015–3989; Directorate Identifier 2014–NM–250–AD.

(a) Effective Date

This AD is effective September 16, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the airplanes identified in paragraphs (c)(1), (c)(2), (c)(3), and (c)(4) of this AD; certificated in any category; all manufacturer serial numbers, except those that have embodied Airbus modification 33125 (gaseous system for all oxygen containers) in production.

(1) Airbus Model A318–111, –112, –121, and –122 airplanes.

(2) Airbus Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes.

(3) Airbus Model A320–211, –212, –214, –231, –232, and –233 airplanes.

(4) Airbus Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 35, Oxygen.

(e) Reason

This AD was prompted by reports of premature aging of certain passenger chemical oxygen generators that resulted in the generators failing to activate. We are issuing this AD to prevent failure of the passenger chemical oxygen generator to activate and consequently not deliver oxygen during an emergency, possibly resulting in injury to the airplane occupants.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Part Number Inspection

Within 30 days after the effective date of this AD: Do a one-time inspection of passenger chemical oxygen generators, part numbers (P/N) 117042–02 (15 minutes (min)—2 masks), 117042–03 (15 min—3 masks), 117042–04 (15 min—4 masks), 117042–22 (22 min—2 masks), 117042–23 (22 min—3 masks), and 117042–24 (22 min—4 masks) to determine the date of manufacture as specified in Airbus Alert Operators Transmission (AOT) A35N006–14, dated December 10, 2014, including Appendix 1. Refer to figures 1 and 2 to paragraph (g) of this AD for the location of the date. A review of airplane maintenance records is acceptable for the inspection required by this paragraph, provided the date of manufacture can be conclusively determined by that review.

Figure 1 to Paragraph (g) of this AD - Location of Date (MM-YY)

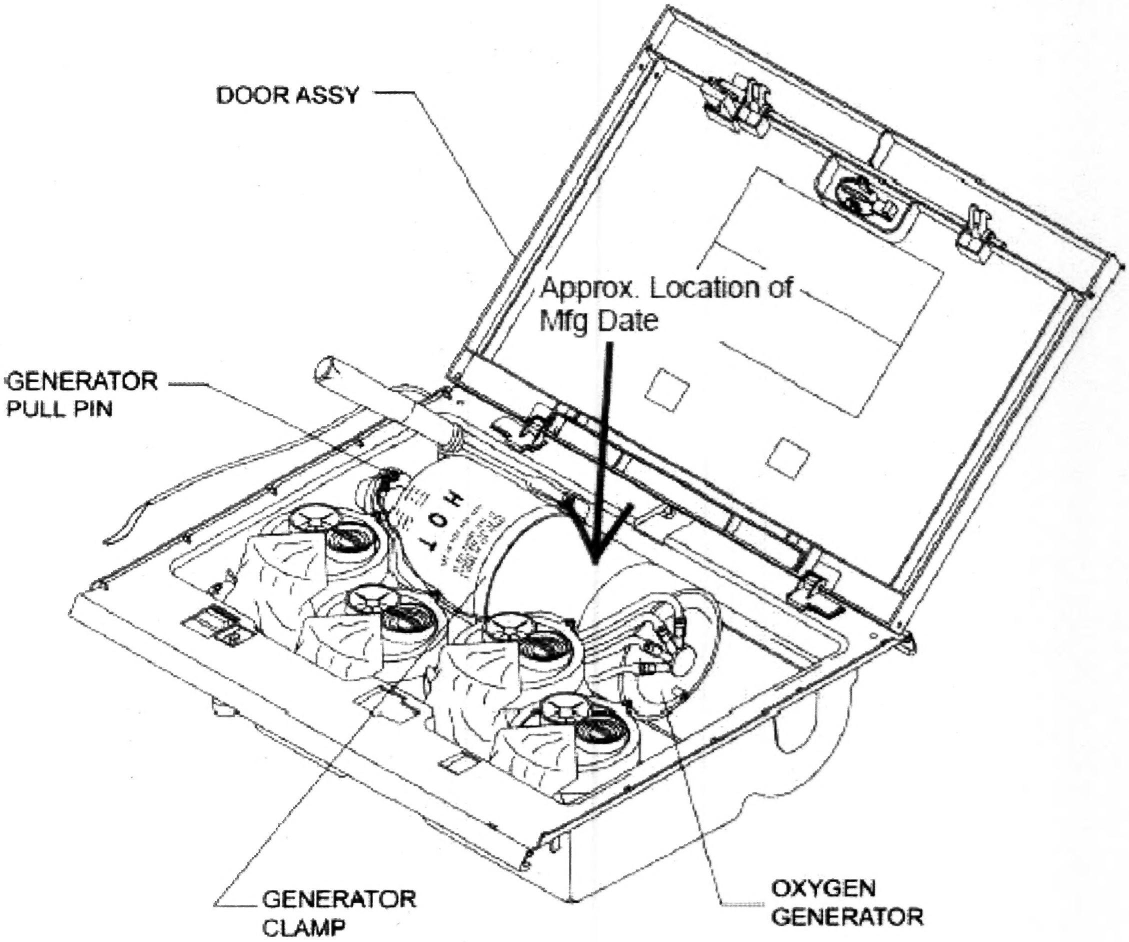
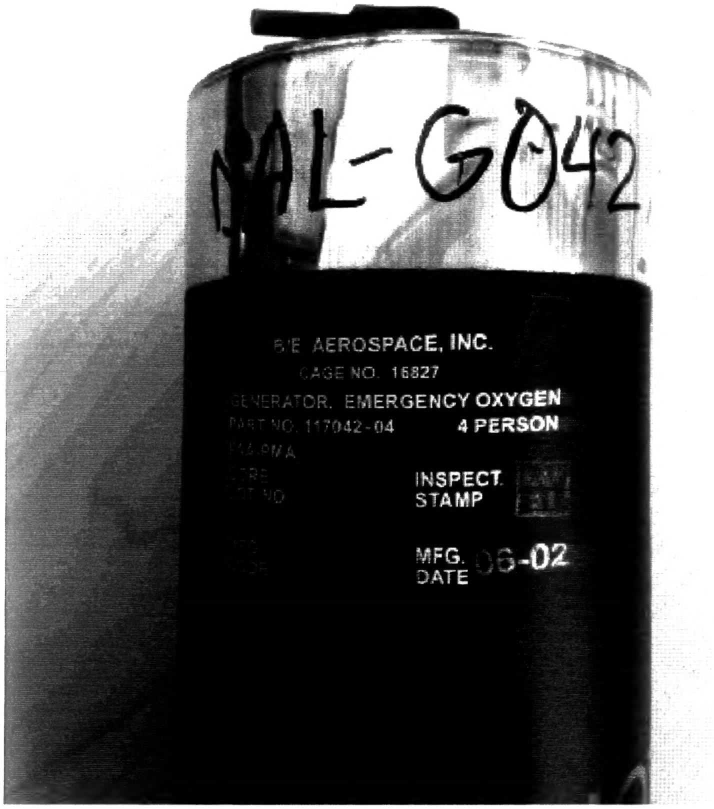

DOOR ASSY
Approx. Location of Mfg Date
GENERATOR PULL PIN
HOT
GENERATOR CLAMP
OXYGEN GENERATOR

Figure 2 to Paragraph (g) of this AD - MFG.DATE (06-02 = June 2002) Example



(h) Replacement of Passenger Chemical Oxygen Generators Manufactured in 1999, 2000, or 2001

If, during any inspection required by paragraph (g) of this AD, any passenger chemical oxygen generator having a date of manufacture in 1999, 2000, or 2001 is found: At the applicable time specified in paragraph (h)(1), (h)(2), or (h)(3) of this AD, remove and replace the affected passenger chemical oxygen generator with a serviceable unit, in accordance with Airbus AOT A35N006–14, dated December 10, 2014, including Appendix 1 (for 15-minute and 22-minute passenger chemical oxygen generators); or the Accomplishment Instructions of B/E Aerospace Service Bulletin 117042–35–001, Revision 004, dated October 13, 2015 (for 15-minute passenger chemical oxygen generators).

(1) For passenger chemical oxygen generators that have a date of manufacture in 1999: Within 30 days after the effective date of this AD.

(2) For passenger chemical oxygen generators that have a date of manufacture in 2000: Within 6 months after the effective date of this AD.

(3) For passenger chemical oxygen generators that have a date of manufacture in 2001: Within 12 months after the effective date of this AD.

(i) Replacement of Passenger Chemical Oxygen Generators Manufactured in 2002 and Later

If, during any inspection required by paragraph (g) of this AD, any passenger chemical oxygen generator having a date specified in table 1 to paragraph (i) of this AD is found: At the applicable time specified in table 1 to paragraph (i) of this AD, remove and replace the affected passenger chemical oxygen generator with a serviceable unit, in accordance with Airbus AOT A35N006–14, dated December 10, 2014, including Appendix 01, undated (for 15-minute and 22-minute passenger chemical oxygen generators); or the Accomplishment Instructions of B/E Aerospace Service Bulletin 117042–35–001, Revision 004, dated October 13, 2015 (for 15-minute passenger chemical oxygen generators).

TABLE 1 TO PARAGRAPH (i) OF THIS AD—REPLACEMENT COMPLIANCE TIMES

Year of manufacture	Compliance time
2002	Within 12 months after the effective date of this AD.
2003	Within 16 months after the effective date of this AD.
2004	Within 20 months after the effective date of this AD.
2005	Within 24 months after the effective date of this AD.
2006	Within 28 months after the effective date of this AD.

TABLE 1 TO PARAGRAPH (i) OF THIS AD—REPLACEMENT COMPLIANCE TIMES—Continued

Year of manufacture	Compliance time
2007	Within 32 months after the effective date of this AD.
2008	Within 36 months after the effective date of this AD.
2009	Before exceeding 10 years since date of manufacture of the passenger chemical oxygen generator.

(j) Definition of Serviceable

For the purpose of this AD, a serviceable unit is a passenger chemical oxygen generator having P/N 117042–XX with a manufacturing date not older than 10 years, or any other approved part number, provided that the generator has not exceeded the life limit established for that generator by the manufacturer.

(k) Reporting

At the applicable time specified in paragraph (k)(1) or (k)(2) of this AD, submit a report of the findings (both positive and negative) of the inspection required by paragraph (g) of this AD, in accordance with paragraph 7, "Reporting," of Airbus AOT A35N006–14, dated December 10, 2014, including Appendix 1. The report must include the information specified in Appendix 1 of Airbus AOT A35N006–14, dated December 10, 2014.

(1) If the inspection was done on or after the effective date of this AD: Submit the report within 30 days after the inspection.

(2) If the inspection was done before the effective date of this AD: Submit the report within 30 days after the effective date of this AD.

(l) Parts Installation Limitation

As of the effective date of this AD, no person may install a passenger chemical oxygen generator, unless it is determined, prior to installation, that the oxygen generator is a serviceable unit as specified in paragraph (j) of this AD.

(m) Credit for Previous Actions

This paragraph provides credit for actions required by paragraphs (h) and (i) of this AD, if those actions were performed before the effective date of this AD using the service information specified in paragraphs (m)(1), (m)(2), (m)(3), or (m)(4).

(1) B/E Aerospace Service Bulletin 117042–35–001, dated December 10, 2014.

(2) B/E Aerospace Service Bulletin 117042–35–001, Revision 001, dated April 9, 2015.

(3) B/E Aerospace Service Bulletin 117042–35–001, Revision 002, dated May 29, 2015.

(4) B/E Aerospace Service Bulletin 117042–35–001, Revision 003, dated June 25, 2015.

(n) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Sanjay Ralhan, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone: 425–227–1405; fax: 425–227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Reporting Requirements:* A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES–200.

(o) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) European Aviation Safety Agency (EASA) AD 2015–0117, dated June 24, 2015; corrected August 7, 2015; for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–3989.

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (p)(3) and (p)(4) of this AD.

(p) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Airbus Alert Operators Transmission A35N006–14, dated December 10, 2014, including Appendix 01, undated.

(ii) B/E Aerospace Service Bulletin 117042–35–001, Revision 004, dated October 13, 2015.

(3) For Airbus service information identified in this AD, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone: +33 5 61 93 36 96; fax: +33 5 61 93 44 51; email: *account.airworth-eas@airbus.com;* Internet: *http://www.airbus.com.* For B/E Aerospace service information identified in this AD, contact B/E Aerospace Inc., 10800 Pflumm Road, Lenexa, KS 66215; telephone: 913–338–9800; fax: 913–469–8419; Internet: *http://beaerospace.com/home/globalsupport.*

(4) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on July 21, 2016.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–18169 Filed 8–11–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2016–5456; Airspace Docket No. 16–AGL–11]

Establishment of Class E Airspace; Linton, ND

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E en route domestic airspace in the Linton, ND, area. Controlled airspace is necessary at Linton Municipal Airport to facilitate vectoring of Instrument Flight Rules (IFR) aircraft under control of Minneapolis Air Route Traffic Control Center (ARTCC). This action enhances the safety and management of IFR operations within the National Airspace System (NAS).

DATES: Effective 0901 UTC, November 10, 2016. The Director of the Federal Register approves this incorporation by reference action under title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.9Z, Airspace Designations and Reporting Points, and subsequent amendments can be viewed on line at *http://www.faa.gov/airtraffic/publications/*. For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: 202–267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal-regulations/ibr_locations.html*.

FAA Order 7400.9, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Raul Garza, Jr., Central Service Center, Operations Support Group, Federal Aviation Administration, Southwest Region, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone: (817) 222–5874.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part, A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it establishes controlled airspace at Linton Municipal Airport, Linton, ND.

History

On May 6, 2016, the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) to establish Class E Airspace at Linton Municipal Airport, Linton, ND (81 FR 27356) Docket No. FAA–2016–5456. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. One comment in support of the proposal was received from the National Business Aviation Association.

Class E airspace designations are published in paragraph 6006 of FAA Order 7400.9Z dated August 6, 2015, and effective September 15, 2015, which is incorporated by reference in 14 CFR part 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.9Z, airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015. FAA Order 7400.9Z is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.9Z lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 establishes Class E airspace extending upward from 1,200 feet above the surface within a 125-mile radius of Linton Municipal Airport, Linton, ND, to facilitate vectoring of IFR aircraft under control of Minneapolis ARTCC. Controlled airspace is needed for the safety and management of IFR operations within the NAS.

Class E airspace designations are published in Paragraph 6006 of FAA Order 7400.9Z, dated August 6, 2015, and effective September 15, 2015, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, "Environmental Impacts: Policies and Procedures," paragraph 5–6.5a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exists that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120, E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, effective September 15, 2015, is amended as follows:

Paragraph 6006 En Route Domestic Airspace Areas.

* * * * *

AGL ND E6 Linton, ND [New]

Linton Municipal Airport
(Lat. 46°13′14″ N., long. 100°14′44″ W.)

That airspace extending upward from 1,200 feet above the surface within a 125-mile radius of Linton Municipal Airport.

Issued in Fort Worth, TX, on July 29, 2016.

Robert W. Beck,

Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2016–19011 Filed 8–11–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2016–5386; Airspace Docket No. 16–AGL–12]

Establishment of Class E Airspace; Platte, SD

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E en route domestic airspace in the Platte, SD, area. Controlled airspace is necessary at Platte Municipal Airport to facilitate vectoring of Instrument Flight Rules (IFR) aircraft under control of Minneapolis Air Route Traffic Control Center (ARTCC). This action enhances the safety and management of IFR operations within the National Airspace System (NAS).

DATES: Effective 0901 UTC, November 10, 2016. The Director of the Federal Register approves this incorporation by reference action under title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.9Z, Airspace Designations and Reporting Points, and subsequent amendments can be viewed on line at *http://www.faa.gov/airtraffic/publications/*. For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: 202–267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal-regulations/ibr_locations.html*.

FAA Order 7400.9, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Raul Garza, Jr., Central Service Center, Operations Support Group, Federal Aviation Administration, Southwest Region, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone: (817) 222–5874.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part, A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it establishes controlled airspace at Platte Municipal Airport, Platte, SD.

History

On May 6, 2016, the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) to establish Class E Airspace in the Platte, SD area. (81 FR 27355) Docket No. FAA–2016–5386. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. One comment in support of the proposal was received from the National Business Aviation Association.

Class E airspace designations are published in paragraph 6006 of FAA Order 7400.9Z dated August 6, 2015, and effective September 15, 2015, which is incorporated by reference in 14 CFR part 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.9Z, airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015. FAA Order 7400.9Z is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.9Z lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 establishes Class E airspace extending upward from 1,200 feet above the surface within a 75-mile radius of Platte Municipal Airport, Platte, SD, to facilitate vectoring of IFR aircraft under control of Minneapolis ARTCC. Controlled airspace is needed for the safety and management of IFR operations within the NAS.

Class E airspace designations are published in Paragraph 6006 of FAA Order 7400.9Z, dated August 6, 2015, and effective September 15, 2015, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, "Environmental Impacts: Policies and Procedures," paragraph 5–6.5a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exists that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120, E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, effective September 15, 2015, is amended as follows:

Paragraph 6006 En Route Domestic Airspace Areas.

* * * * *

AGL SD E6 Platte, SD [New]

Platte Municipal Airport
(Lat. 43°24′17″ N., long. 098°49′50″ W.)

That airspace extending upward from 1,200 feet above the surface within a 75-mile radius of Platte Municipal Airport.

Issued in Fort Worth, TX, on July 29, 2016.

Robert W. Beck,

Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2016–18996 Filed 8–11–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2016–1074; Airspace Docket No. 16–ASO–3]

Revocation of Class D Airspace; North, SC

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action removes Class D Airspace at North, SC, as the North Air Force Auxiliary Field Air Traffic Control Tower is no longer staffed, and the controlled Class D airspace area is no longer required.

DATES: Effective 0901 UTC, November 10, 2016. The Director of the Federal Register approves this incorporation by reference action under Title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.9Z, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/airtraffic/publications/*. For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: 202–267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.9Z at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal-regulations/ibr_locations.html*.

FAA Order 7400.9, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–6364.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part, A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it removes Class D airspace at North Air Force Auxiliary Field, North, SC.

History

On March 28, 2016, the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) to remove Class D airspace at North Air Force Auxiliary Field, North, SC., (81 FR 17111) FAA 2016–1074. No comments were received.

Class D airspace designations are published in paragraphs 5000 of FAA Order 7400.9Z dated August 6, 2015, and effective September 15, 2015, which is incorporated by reference in 14 CFR part 71.1. The Class D airspace designations listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015. FAA Order 7400.9Z is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.9Z lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 removes Class D airspace at North Air Force Auxiliary Field, North, SC. The air traffic control tower is no longer in use. Therefore, the Class D airspace area is no longer necessary.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, "Environmental Impacts: Policies and Procedures," paragraph 5–6.5a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120, E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, effective September 15, 2015, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

ASO SC D North, SC [Removed]

Issued in College Park, Georgia, on August 4, 2016.

Joey L. Medders,

Acting Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2016–19001 Filed 8–11–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2016–5387; Airspace Docket No. 16–AGL–13]

Establishment of Class E Airspace; Harvey, ND

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E en route domestic airspace in the Harvey, ND, area for Harvey Municipal Airport. Controlled airspace is necessary to facilitate vectoring of Instrument Flight Rules (IFR) aircraft under control of Minneapolis Air Route Traffic Control Center (ARTCC). This action enhances the safety and efficiency of aircraft operations within the National Airspace System.

DATES: Effective 0901 UTC, November 10, 2016. The Director of the Federal Register approves this incorporation by reference action under title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.9Z, Airspace Designations and Reporting Points, and subsequent amendments can be viewed on line at *http://www.faa.gov/airtraffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: 202–267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal-regulations/ibr_locations.html.*

FAA Order 7400.9, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Raul Garza, Jr., Central Service Center, Operations Support Group, Federal Aviation Administration, Southwest Region, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone: (817) 222–5874.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part, A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it establishes controlled airspace at Harvey Municipal Airport, Harvey, ND.

History

On May 6, 2016, the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) to establish Class E Airspace in the Harvey, ND area. (81 FR 27357) Docket No. FAA–2016–5387. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. One comment in support of the proposal was received the National Business Aviation Association.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.9Z, airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015. FAA Order 7400.9Z is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.9Z lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 establishes Class E airspace extending upward from 1,200 feet above the surface within a 100-mile radius of Harvey Municipal Airport, Harvey, ND, to facilitate vectoring of IFR aircraft under control of Minneapolis ARTCC. Controlled airspace is needed for the safety and management of IFR operations in the National Airspace System.

Class E airspace designations are published in Paragraph 6006 of FAA Order 7400.9Z, dated August 6, 2015, and effective September 15, 2015, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, "Environmental Impacts: Policies and Procedures," paragraph 5–6.5a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exists that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120, E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, effective September 15, 2015, is amended as follows:

Paragraph 6006 En Route Domestic Airspace Areas.

* * * * *

AGL ND E6 Harvey, ND [New]

Harvey Municipal Airport, ND
(Lat. 47°47′28″ N., long. 099°55′54″ W.)

That airspace extending upward from 1,200 feet above the surface within a 100-mile radius of Harvey Municipal Airport, excluding that airspace within Canada.

Issued in Fort Worth, TX, on August 3, 2016.

Vonnie L. Royal,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2016–19006 Filed 8–11–16; 8:45 am]

BILLING CODE 4910–13–P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 1

RIN 3038–AE48

Written Acknowledgment of Customer Funds From Federal Reserve Banks

AGENCY: Commodity Futures Trading Commission.

ACTION: Final rule.

SUMMARY: The Commodity Futures Trading Commission ("CFTC" or "Commission") is amending its regulations to revise or repeal certain provisions related to the requirement that a derivatives clearing organization ("DCO") obtain from a Federal Reserve Bank acting as a depository for customer funds a written acknowledgment that the Federal Reserve Bank was informed that the customer funds deposited therein are those of customers and are being held in accordance with Section 4d of the Commodity Exchange Act ("CEA").

DATES: Effective August 12, 2016.

FOR FURTHER INFORMATION CONTACT: Eileen A. Donovan, Deputy Director, 202–418–5096, *edonovan@cftc.gov;* M. Laura Astrada, Associate Director, 202–418–7622, *lastrada@cftc.gov;* or Parisa Abadi, Attorney-Advisor, 202–418–6620, *pabadi@cftc.gov,* in each case, at the Division of Clearing and Risk, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581.

SUPPLEMENTARY INFORMATION: On June 2, 2016, the Commission published for public comment in the **Federal Register** a proposed order that would exempt Federal Reserve Banks that provide customer accounts and other services to certain designated financial market utilities registered with the Commission from Sections 4d and 22 of the CEA.[1] The proposed order would permit Federal Reserve Banks to hold money, securities, and property deposited into a customer account by certain designated financial market utilities in accordance with the standards to which Federal Reserve Banks are held.

In response to the request for public comment, CME Group Inc. noted that the proposed order would be inconsistent with Regulation 1.20(g)(4)(ii).[2] Commission Regulation 1.20(g)(4)(ii) requires that a DCO obtain from a Federal Reserve Bank acting as a depository for customer funds a written acknowledgment that the customer funds deposited therein are being held in accordance with Section 4d of the CEA; however, pursuant to the terms of the proposed order, the Federal Reserve Banks would be exempt from Section 4d. The Commission subsequently issued a final exemptive order that is substantively similar to the proposed order. In the **Federal Register** notice issuing the final exemptive order, the Commission noted that, in light of the comment, it had determined to repeal the written acknowledgment requirement with respect to customer accounts held with a Federal Reserve Bank[3] in a separate **Federal Register** notice. The final exemptive order will render these provisions inapplicable, as the Federal Reserve Banks will not be held to the requirements of Section 4d of the CEA. Therefore, the Commission is amending Regulation 1.20 to remove the acknowledgment letter requirement for customer funds deposited by a DCO with a Federal Reserve Bank. The Commission welcomes any comments and/or questions regarding this amendment.

List of Subjects in 17 CFR Part 1

Brokers, Commodity futures, Consumer protection, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, the Commodity Futures Trading Commission amends 17 CFR part 1 as follows:

PART 1—GENERAL REGULATIONS UNDER THE COMMODITY EXCHANGE ACT

■ 1. The authority citation for part 1 continues to read as follows:

Authority: 7 U.S.C. 1a, 2, 5, 6, 6a, 6b, 6c, 6d, 6e, 6f, 6g, 6h, 6i, 6k, 6l, 6m, 6n, 6o, 6p, 6r, 6s, 7, 7a–1, 7a–2, 7b, 7b–3, 8, 9, 10a, 12, 12a, 12c, 13a, 13a–1, 16, 16a, 19, 21, 23, and 24 (2012).

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[1] Notice of Proposed Order and Request for Comment on Proposal to Exempt, Pursuant to the Authority in Section 4(c) of the Commodity Exchange Act, the Federal Reserve Banks from Sections 4d and 22 of the Commodity Exchange Act, 81 FR 35337 (June 2, 2016).

[2] 17 CFR 1.20(g)(4)(ii). Regulation 1.20(g)(4)(ii) provides that a DCO shall obtain from a Federal Reserve Bank only a written acknowledgment that: (A) The Federal Reserve Bank was informed that the customer funds deposited therein are those of customers and are being held in accordance with the provisions of section 4d of the Act and Commission regulations thereunder; and (B) The Federal Reserve Bank agrees to reply promptly and directly to any request from Commission staff for confirmation of account balances or provision of any other information regarding or related to an account. *Id.*

[3] Specifically, the Commission is revising paragraphs (g)(4)(i) and (g)(4)(ii) of Regulation 1.20, and repealing paragraphs (g)(4)(ii)(A) and (g)(4)(ii)(B) of Regulation 1.20.

■ 2. Amend § 1.20 by revising paragraphs (g)(4)(i) and (ii) to read as follows:

§ 1.20 Futures customer funds to be segregated and separately accounted for.

* * * * *

(g) * * *

(4) * * *

(i) A derivatives clearing organization must obtain a written acknowledgment from each depository prior to or contemporaneously with the opening of a futures customer funds account; *provided, however,* that a derivatives clearing organization is not required to obtain a written acknowledgment from a Federal Reserve Bank with which it has opened a futures customer funds account.

(ii) The written acknowledgment must be in the form as set out in appendix B to this part.

* * * * *

Issued in Washington, DC, on August 8, 2016, by the Commission.

Christopher J. Kirkpatrick,

Secretary of the Commission.

Note: The following appendices will not appear in the Code of Federal Regulations.

Appendices to Written Acknowledgment of Customer Funds From Federal Reserve Banks—Commission Voting Summary, Chairman's Statement, and Commissioner's Statement

Appendix 1—Commission Voting Summary

On this matter, Chairman Massad and Commissioners Bowen and Giancarlo voted in the affirmative. No Commissioner voted in the negative.

Appendix 2—Statement of Chairman Timothy G. Massad

Today, the Commission continues its work to ensure the resiliency of clearinghouses and protect customers in our markets. To provide the necessary context for these efforts, it is useful to look back at recent history.

Most participants in our markets will recall what happened at the beginning of the financial crisis in September 2008, when the Reserve Fund—a money market fund—"broke the buck" following the bankruptcy of Lehman Brothers. Redemptions were suspended and investors were not able to make withdrawals. As a result, many futures commission merchants (FCMs) were not able to access customer funds invested in the Reserve Fund. Absent relief by the CFTC, many would have been undercapitalized, potentially ending up in bankruptcy. In addition, clearinghouses could not liquidate investments in the Reserve Fund. And there could have easily been a widespread run on money market funds, but for the emergency actions taken by the U.S. government.

As a result of the crisis, as well as the collapse of MF Global, the CFTC and our self-regulatory organizations took a number of actions to better protect customer funds. We required customer funds to be strictly segregated and limited the ways they can be invested. We enhanced accounting and auditing procedures at FCMs, including by requiring daily verification from depositories of the amounts deposited by FCMs.

Today, CFTC rules require that customer funds be invested in highly liquid assets and be convertible into cash within one business day without a material discount in value. Our rules also require that clearinghouses invest initial margin deposits in a manner that allows them to promptly liquidate any such investment.

Over the last few years, the Securities and Exchange Commission (SEC) has also taken action in response to the lessons of the financial crisis, by adopting a number of measures to address the potential vulnerabilities of money market funds. One such recent reform, which takes effect in October of this year, sets forth the circumstances where prime money market funds are permitted, or in some circumstances required, to suspend redemptions in order to prevent the risk of investor runs.

While we recognize the benefit of the SEC's new rule in preventing investor runs, a suspension of redemptions by a money market fund would mean investments in such funds are not accessible and cannot be promptly liquidated. Such an event could result in customers, FCMs, and clearinghouses being unable to access the funds necessary to satisfy margin obligations.

Therefore, CFTC staff is today providing guidance making clear that Commission rules prohibit a clearing member from investing customer funds, or a clearinghouse from investing amounts deposited as initial margin, in such money market funds.

Some industry participants have suggested we should interpret or revise our rules to permit investments of at least some customer monies in such money market funds unless and until redemptions are suspended. We have declined to do so, as it would be too late to protect customers at that point. Moreover, there are alternatives to prime funds, including certain government money markets funds or Treasury securities. In fact, investments in prime money market funds represent a relatively small portion of the total customer funds on deposit and the total initial margin deposits at clearinghouses. Some of our clearinghouses and FCMs do not have any investments in prime funds.

Staff has been careful not to be overly restrictive, and therefore has issued no-action relief to allow FCMs to invest certain "excess" proprietary funds held in customer accounts in these money market funds. That is, our existing rules require FCMs to deposit their own funds (*i.e.*, targeted residual interest) into customer accounts to make sure that there are sufficient funds in the segregated customer accounts to cover all obligations due to customers. FCMs frequently deposit an amount of their own funds that is in excess of the targeted residual interest amount required under our rules, and that excess amount can be withdrawn at any time. Indeed, if an FCM should default, customers—and the system as a whole—are better off if excess funds are on deposit, and we do not wish to incentivize FCMs to withdraw such excess funds from the segregated account. Therefore, the no action relief makes clear that FCMs can continue to invest their own funds in excess of their targeted residual interest in such money market funds, even though they cannot invest the customer funds—or any proprietary funds they are required to deposit—in this manner.

Finally, the Commission is taking action today that will further ensure the safety of customer funds. We are issuing an order that will help make it possible for systemically important clearinghouses to deposit customer funds at Federal Reserve Banks. Our order makes clear that a Federal Reserve Bank that opens such an account would be subject to the same standards of liability that generally apply to it as a depository, rather than any potentially conflicting standard under the commodity laws.

Although Federal Reserve accounts for customer funds held by systemically important clearinghouses do not exist today, they are allowed under the Dodd-Frank Act, and we have been working with the Board of Governors to facilitate them. The two clearinghouses designated as systemically important in our markets have been approved to open Federal Reserve Bank accounts for their proprietary funds. We hope that with today's action, accounts for customer funds can be opened soon. Doing so will help protect customer funds and enhance the resiliency of clearinghouses.

I thank the dedicated CFTC staff and my fellow Commissioners for their work on these matters.

Appendix 3—Concurring Statement of Commissioner Sharon Y. Bowen

I am pleased to concur with the two Commission actions: the "Order Exempting the Federal Reserve Banks from Sections 4d and 22 of the Commodity Exchange Act" and "Written Acknowledgment of Customer Funds from Federal Reserve Banks." I have long believed that, in order to protect customer funds, we need to keep that money at our central bank. In the event of a major market event, I, and I believe the rest of the American people, would feel much better knowing that investors' money is at the Federal Reserve instead of at multiple central counterparties. I am glad that our agency and the Federal Reserve have come to an agreement on an effective way to accomplish this.

I am similarly pleased with the Division of Clearing and Risk's (DCR) "Staff Interpretation Regarding CFTC Part 39 In Light Of Revised SEC Rule 2a–7," which clearly outlines the staff's understanding that, given the limitations that the Securities and Exchange Commission (SEC) has imposed on redemptions for prime money market funds, that they are no longer considered Rule 1.25 assets. This is the correct interpretation. The key feature in a Rule 1.25 asset is that it must be available quickly in times of crisis or illiquidity. And we know that funds are more likely to close the gates on redemptions when market dislocation happens. That is just the time when futures commission merchants (FCMs) and customers would need access to their money, and a multi-day delay can mean catastrophe for some businesses.

For that very reason, I have concerns about the Division of Swap Dealer and Intermediary Oversight's (DSIO) "No-Action Relief With Respect to CFTC Regulation 1.25 Regarding Money Market Funds." While the 4(c) exemption and the DCR interpretation are clearly customer protection initiatives, the DSIO no action letter is not. This no action letter would allow FCMs to keep money in segregated customer accounts that actually would not be readily available in a crisis. Thus, while it may appear that an FCM had considerable funds available to settle customer accounts during a market dislocation, in fact that would be only be an illusion; a portion of those funds could be locked down behind the prime money market funds' gates and therefore not actually be available when needed.

I do not think that the staff of the Commission should be supporting this kind of "window dressing"—giving the impression of greater security than there actually is. If the funds are not suitable investments for customer funds, then they are not suitable for the additional capital that the FCMs put in those accounts to protect against potential shortfalls. Having lived through bankruptcies, such as MF Global and Peregrine, I have a healthy respect for the importance of having strong clearing members with a large cushion of funds that can be accessed when needed. This no action letter undermines that effort. Given the importance of this topic to the general public, we should at least have asked for comments or even held a roundtable before making this change. I therefore hope to reexamine this subject in the near future.

[FR Doc. 2016–19211 Filed 8–11–16; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1926

[Docket No. OSHA–2007–0026]

RIN 1218–AB47

Confined Spaces in Construction; Approval of Collections of Information

AGENCY: Occupational Safety and Health Administration (OSHA), Department of Labor.

ACTION: Final rule.

SUMMARY: This rule is a technical amendment revising OSHA's regulations to reflect the approval by the Office of Management and Budget (OMB) of the collections of information contained in OSHA's standard for Confined Spaces in Construction.

DATES: Effective August 12, 2016.

FOR FURTHER INFORMATION CONTACT: Todd Owen, OSHA, Directorate of Standards and Guidance, Room N–3609, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–2222.

SUPPLEMENTARY INFORMATION: OSHA published a final rule for Confined Spaces in Construction on May 4, 2015 (80 FR 25365) to provide new protections to employees working in confined spaces in construction. This new subpart replaced OSHA's general training requirement for work in confined spaces (29 CFR 1926.21(b)(6)) with a comprehensive standard. The new standard includes a permit program designed to protect employees from exposure to many hazards associated with work in confined spaces, including atmospheric and physical hazards. Those requirements contained collections of information approved by OMB under control number 1218–0258, which OSHA publicized in the **Federal Register** document announcing the new rule (see 80 FR 22514–22517). This technical amendment codifies the OMB control number for the Confined Spaces in Construction standard into § 1926.5, which is the central section in which OSHA displays its approved collections under the Paperwork Reduction Act.

Additional opportunity for public comment on this rule is unnecessary because the public has already had the opportunity to comment on the collections of information and OMB has approved them. This revision of § 1926.5 is a purely technical step to increase public awareness of OMB's approval of the collections of information.

Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order 1–2012 (77 FR 3912 (1/25/2012)).

List of Subjects in 29 CFR Part 1926

Occupational safety and health, Reporting and recordkeeping requirements.

Signed at Washington, DC, on August 2, 2016.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

For the reasons stated in the preamble in this document, the Occupational Safety and Health Administration amends 29 CFR part 1926 as follows:

PART 1926—SAFETY AND HEALTH REGULATIONS FOR CONSTRUCTION

Subpart A—General

■ 1. The authority citation for part 1926, subpart A, continues to read as follows:

Authority: 40 U.S.C. 3701 *et seq.*; 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), or 5–2007 (72 FR 31160), 5–2007 (72 FR 31160), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912), as applicable; and 29 CFR part 1911.

■ 2. Amend § 1926.5 by adding to the table, in the proper numerical sequence, the entries for "1926.1203," "1926.1204," "1926.1205," "1926.1206," "1926.1207," "1926.1208," "1926.1209," "1926.1210," "1926.1211," "1926.1212," and "1926.1213" to read as follows:

§ 1926.5 OMB control numbers under the Paperwork Reduction Act.

* * * * *

29 CFR Citation	OMB Control No.
* * *	* *
1926.1203	1218–0258
1926.1204	1218–0258
1926.1205	1218–0258
1926.1206	1218–0258
1926.1207	1218–0258
1926.1208	1218–0258
1926.1209	1218–0258
1926.1210	1218–0258
1926.1211	1218–0258
1926.1212	1218–0258
1926.1213	1218–0258
* * *	* *

[FR Doc. 2016–18965 Filed 8–11–16; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2016–0541]

RIN 1625–AA08

Special Local Regulation; Allegheny River Mile 0.0–1.5; Pittsburgh, PA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a special local regulation for all waters of the Allegheny River mile 0.0–1.5. This special local regulation is necessary to provide safety for the participants in the "Pittsburgh Triathlon and Adventure Race" marine event. This rulemaking prohibits persons and vessels from being in the special local regulated area unless authorized by the Captain of the Port Pittsburgh or a designated representative.

DATES: This rule is effective from 6 a.m. on August 13, 2016, through 9 a.m. on August 14, 2016.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2016–0541 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email MST1 Jennifer Haggins, Marine Safety Unit Pittsburgh, U.S. Coast Guard, at telephone 412–221–0807, email *Jennifer.L.Haggins@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR	Code of Federal Regulations
FR	Federal Register
NPRM	Notice of proposed rulemaking
§	Section
U.S.C.	United States Code

II. Background Information and Regulatory History

This annually recurring event and special local regulation is currently listed as the "Friends of the Riverfront Inc./Pittsburgh Triathlon and Adventure Races" under 33 CFR 100.801, Table 1, line no. 21, scheduled for two days during the last two weekends in July or first weekend of August. This year the event sponsor changed the date to the second weekend of August, and informed the Coast Guard of this date change on June 6. The event will consist of at least 400 swimmers and takes place on the Allegheny River. This temporary final rule reflects the date changes to the event. The Captain of the Port Pittsburgh (COTP) has determined that the special local regulation under 33 CFR 100.801 is still necessary to protect participants, spectators, and waterway users during this event.

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." It is impracticable to publish an NPRM because we must establish this special local regulation by August 13, 2016.

We are issuing this rule, and under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making it effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to public interest because immediate action is needed to establish a special local regulation to protect participants of the "Pittsburgh Triathlon and Adventure Race" beginning on August 13, 2016 to August 14, 2016.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1233. The Captain of the Port Pittsburgh (COTP) has determined the need to protect participants during the "Pittsburgh Triathlon and Adventure Race" from 6 a.m. to 9 a.m. on August 13, 2016 and August 14, 2016. This rule is needed to protect personnel, vessels, and these navigable waters before, during, and after the scheduled event.

IV. Discussion of the Rule

The Captain of the Port Pittsburgh is establishing this special local regulated area from 6 a.m. to 9 a.m. on August 13, 2016 and August 14, 2016 for all waters of the Allegheny River mile 0.0–1.5. The duration of the special local regulated area is intended to ensure the safety of vessels, participants, spectators and other waterway users before, during, and after the scheduled event. No vessel or person is permitted to enter the special local regulated area without obtaining permission from the COTP or a designated representative. The regulatory text we are establishing appears at the end of this document.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget.

This regulatory action determination is based on the size, location, duration, and time-of-day of the special local regulated area.

This special local regulation restricts transit on the Allegheny River from mile 0.0–1.5 for a short duration of 3 hours each day. Vessel traffic will be informed about the special local regulated area through local notices to mariners. Moreover, the Coast Guard will issue Broadcast Notices to Mariners via VHF–FM marine channel 16 about the area and the rule allows vessels to seek permission to transit the area.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the special local regulated area may be small entities, for the reasons stated in section V.A above this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves special local regulated area that would prohibit entry to unauthorized vessels. It is categorically excluded from further review under paragraph 34(h) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, and Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERWAYS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233.

■ 2. Add § 100.35T08–0541 to read as follows:

§ 100.35T08–0541 Special Local Regulation; Allegheny River Mile 0.0 to 1.5, Pittsburgh, PA.

(a) *Location.* All waters of the Allegheny River beginning at mile marker 0.0 and ending at mile marker 1.5 at Pittsburgh, PA.

(b) *Periods of Enforcement.* This rule will be enforced from 6 a.m. to 9 a.m. on August 13, 2016 and August 14, 2016. The COTP or a designated representative will inform the public through broadcast notice to mariners of the enforcement period for the special local regulation.

(c) *Regulations.* (1) In accordance with the general regulations in § 100.801 of this part, entry into this area is prohibited unless authorized by the COTP or a designated representative.

(2) Persons or vessels requiring entry into or passage through the area must request permission from the COTP or a designated representative. The COTP representative may be contacted at 412–221–0807.

L. McClain, Jr.,

Commander, U.S. Coast Guard, Captain of the Port Pittsburgh.

[FR Doc. 2016–19138 Filed 8–11–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2016–0752]

Drawbridge Operation Regulation; Rockaway Inlet, Queens, NY

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Marine Parkway Bridge across the Rockaway Inlet, mile 3.0, at Queens, New York. This deviation is necessary to allow the bridge owner to replace span guide rollers, counterweight guide shoes and trunnion journal at the bridge.

DATES: This deviation is effective from 7 a.m. on October 17, 2016 to 5 p.m. on October 28, 2016.

ADDRESSES: The docket for this deviation, [USCG–2016–0752] is available at *http://www.regulations.gov*. Type the docket number in the "SEARCH" box and click "SEARCH". Click on Open Docket Folder on the line associated with this deviation.

FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Judy Leung-Yee, Project Officer, First Coast Guard District, telephone (212) 514–4330, email *judy.k.leung-yee@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Marine Parkway Bridge, mile 3.0, across the Rockaway Inlet, has a vertical clearance in the closed position of 55 feet at mean high water and 59 feet at mean low water. The existing bridge operating regulations are found at 33 CFR 117.795(a).

The waterway is transited by commercial barge traffic of various sizes.

The bridge owner, MTA Bridges and Tunnels, requested a temporary deviation from the normal operating schedule to replace span guide rollers, counterweight guide shoes and trunnion journal at the bridge.

Under this temporary deviation, the Marine Parkway Bridge shall remain in the closed position from 7 a.m. on October 17, 2016 to 5 p.m. October 28, 2016.

Vessels able to pass under the bridge in the closed position may do so at anytime. The bridge will not be able to open for emergencies and there is no immediate alternate route for vessels to pass.

The Coast Guard will inform the users of the waterways through our Local Notice and Broadcast to Mariners of the change in operating schedule for the bridge so that vessel operations can arrange their transits to minimize any impact caused by the temporary deviation. The Coast Guard notified various companies of the commercial oil and barge vessels and they have no objections to the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: August 9, 2016.

C.J. Bisignano,

Supervisory Bridge Management Specialist, First Coast Guard District.

[FR Doc. 2016–19189 Filed 8–11–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

Drawbridge Operation Regulations

CFR Correction

■ In Title 33 of the Code of Federal Regulations, Parts 1 to 124, revised as of July 1, 2015, on page 639, in § 117.799, paragraph (j) is removed.

[FR Doc. 2016–19344 Filed 8–11–16; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF EDUCATION

34 CFR Chapter III

[Docket ID ED–2016–OSERS–0018; CFDA Number: 84.160D.]

Final Priority—Training of Interpreters for Individuals Who Are Deaf or Hard of Hearing and Individuals Who Are Deaf-Blind Program

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Final priority.

SUMMARY: The Assistant Secretary for Special Education and Rehabilitative Services announces a final priority under the Training of Interpreters for Individuals Who Are Deaf or Hard of Hearing and Individuals Who Are Deaf-Blind Program. The Assistant Secretary may use this priority for competitions in fiscal year 2016 and later years. We take this action to provide training and technical assistance to better prepare novice interpreters to become highly qualified, nationally certified sign language interpreters.

DATES: This priority is effective September 12, 2016.

FOR FURTHER INFORMATION CONTACT: Kristen Rhinehart-Fernandez, U.S. Department of Education, 400 Maryland Avenue SW., Room 5062, Potomac Center Plaza (PCP), Washington, DC 20202–2800. Telephone: (202) 245–6103 or by email: *Kristen.Rhinehart@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Purpose of Program: Under the Rehabilitation Act of 1973 (Rehabilitation Act), as amended by the Workforce Innovation and Opportunity Act (WIOA), the Rehabilitation Services Administration (RSA) makes grants to public and private nonprofit agencies and organizations, including institutions of higher education, to establish interpreter training programs or to provide financial assistance for ongoing interpreter training programs to train a sufficient number of qualified interpreters throughout the country. The grants are designed to train interpreters to effectively interpret and transliterate using spoken, visual, and tactile modes of communication; ensure the maintenance of the interpreting skills of qualified interpreters; and provide opportunities for interpreters to improve their skills in order to meet both the highest standards approved by certifying associations and the communication needs of individuals who are deaf or hard of hearing and individuals who are Deaf-blind.

Program Authority: 29 U.S.C. 772(f).

Applicable Program Regulations: 34 CFR part 396.

We published a notice of proposed priority (NPP) for this competition in the **Federal Register** on May 6, 2016 (81 FR 27375). That notice contained background information and our reasons for proposing the particular priority.

Public Comment: In response to our invitation in the notice of proposed priority, 25 parties submitted comments on the proposed priority.

We group major issues according to subject. Generally, we do not address technical and other minor changes, or suggested changes the law does not authorize us to make under the applicable statutory authority. In addition, we do not address general comments that raised concerns not directly related to the proposed priority.

Analysis of Comments and Changes: An analysis of the comments and of any changes in the priority since publication of the notice of proposed priority follows.

Specialty Training Supported Through This Priority

Comment: A number of commenters recommended continuing the specialty area training developed in prior grant cycles for deaf-blind interpreting, health care interpreting, legal interpreting, trilingual interpreting in American Sign Language (ASL)/English/Spanish, deaf self-advocacy training (DSAT), interpreting in a Vocational Rehabilitation (VR) setting, interpreting provided by deaf[1] interpreters, and

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[1] As used in this notice, the word "deaf" refers to (1) "deaf" and "Deaf" people, *i.e.*, to the condition of deafness; (2) to "deaf, hard of hearing, and Deaf-Blind"; and (3) to individuals who are

Continued

video remote interpreting and video relay interpreting. The commenters stated that these specialty areas are growing or emerging practice areas and that prior grant cycles only laid the foundation for them. Therefore, commenters recommended the Department of Education (Department) support specialty training in eight specific areas that were funded in prior grant cycles.

First, commenters supported trilingual interpreting in ASL/English/Spanish and argued that there is still a critical need for more training for interpreters in Spanish-influenced settings. One commenter stated that existing training developed for ASL/English/Spanish is still in its very initial stages and, if continued, has the potential to develop model partnerships that could be replicated into a training process for other spoken languages.

Second, commenters supported continued funding for training for deaf-blind interpreting. They indicated that deaf-blind consumers are one of the least well-served groups and there continues to be a critical need to increase the number of interpreters skilled in this area. For example, one commenter shared that there is a new movement occurring within the deaf-blind community around the concept of "pro-tactile," which is altering the nature of communication, language, leadership, and interaction, and is one of the new areas in which interpreters need to be skilled to effectively work with individuals who are deaf-blind.

Finally, one commenter stated that the importance of accessible and advanced training for interpreters in healthcare and legal settings is underscored in a report entitled "Preparing Interpreters for Tomorrow: Report on a Study of Emerging Trends in Interpreting and Implications for Interpreter Education." This report was prepared by a current grantee under this program, the National Interpreter Education Center, Northeastern University, in January 2015. According to this report, interpreters and consumers continue to identify these two specialty areas as areas of priority training needs for interpreters.

Discussion: We agree that there continues to be a critical need for more training in some of the specialty areas funded in the 2010–2016 grant cycle and in earlier cycles. For example, the U.S. Department of Labor predicts that "employment of interpreters and translators is expected to grow 42 percent from 2010 to 2020 and the demand for American Sign Language (ASL) interpreters is expected to grow rapidly. . . ."[2] Therefore, we have concluded that applications may be submitted for specialty training areas developed in the 2010–2016 grant cycles for deaf-blind interpreting, health care interpreting, legal interpreting, trilingual interpreting in ASL/English/Spanish, interpreting in a Vocational Rehabilitation (VR) setting, interpreting provided by Deaf interpreters, and video remote interpreting and video relay interpreting.

Specific to trilingual interpreting, we also believe there may be parts of the country where multiple languages are spoken by deaf individuals. Therefore, we are permitting applicants to address multiple language combinations in their proposals.

However, we believe it would be an inefficient use of Federal resources to allocate funds to focus solely on replicating rather than scaling up or expanding existing training or to train interpreters where there is no need. Therefore, applicants proposing to provide training in existing specialty areas will be expected to describe how their proposed projects expand on, rather than replicate, existing training in these areas. Applications for training in existing specialty areas will also be expected to specify that they plan to serve areas of the country in which there are not enough interpreters to adequately meet the communication needs of deaf, hard-of-hearing, and deaf-blind consumers.

Changes: We revised Specialty Area 2: Trilingual interpreting that immediately follows the application requirements in the priority to allow applicants to submit proposals for trilingual interpreting in ASL/English/Spanish. We added language to the priority requiring applicants that propose to continue existing training in trilingual interpreting for English/Spanish/ASL to provide evidence to support the demand for trilingual interpreters in English/Spanish/ASL and, to the extent possible, specify areas of the country in which there are not enough trilingual English/Spanish/ASL interpreters to adequate meet the communication needs of Deaf, hard-of-hearing, and Deaf-blind consumers. We also added language that applicants proposing to continue existing training in ASL/English/Spanish without improvement, update, or addition of new material will not be eligible for funding.

We added language to Specialty Area 2 to allow applicants to propose multiple language combinations in their proposals. As such, in this specialty area, we will require applicants to propose a framework that will be used to provide trilingual interpreter training and to develop separate modules for each language in order to ensure the training content appropriately addresses the cultural nuances of each language.

Additionally, we revised Specialty Area 3: Field-initiated projects to allow specialty area training for deaf-blind interpreting, health care interpreting, legal interpreting, interpreting in a Vocational Rehabilitation (VR) setting, interpreting provided by Deaf interpreters, and video remote interpreting and video relay interpreting. We added language requiring that applicants ensure that projects will improve, update, and develop new material for training in these specialty areas. We also added language requiring applicants to demonstrate the demand for interpreters in these specialty areas and, to the extent possible, specify areas of the country in which there are not enough interpreters to adequately meet the communication needs of deaf, hard-of-hearing, and deaf-blind consumers. Finally, we added language that applicants proposing to continue existing training in these areas without improvement, update, or addition of new material will not be eligible for funding.

Comments: A number of commenters recommended the Department continue to fund DSAT, which was funded from 2010 to 2016 and in prior grant cycles. Commenters stated that, while the DSAT curriculum is complete and available online, further efforts are necessary to increase training opportunities and ultimately reach more deaf individuals. Some of these commenters also described DSAT's ability to improve the advocacy skills of a deaf person by helping to understand the role of the interpreter, the right to be provided interpreting services, and the impact interpreting services have on obtaining, maintaining, and advancing in competitive integrated employment as well as in other situations. Several commenters argued that those who have gone through the training can more effectively advocate not only for themselves but also for other deaf consumers including those who have dysfluent language. A commenter stated that DSAT directly ties into enhanced employment outcomes and creates jobs for deaf individuals as trainers and

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culturally Deaf and who use ASL. When we use "Deaf," we refer only to the third group.

[2] Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Outlook Handbook, 2012–13 Edition,* Interpreters and Translators, on the Internet at *www.bls.gov/ooh/media-and-communication/interpreters-and-translators.htm* (visited June 3, 2016).

educators in a variety of settings, including secondary and post-secondary education, community-based agencies, and private practice. Finally, a commenter stated that the DSAT curriculum filled a significant gap experienced by educators, VR counselors, and community agency personnel, such as staff from centers for independent living and community rehabilitation programs.

Discussion: We recognize and value DSAT for individuals who are deaf and hard of hearing and individuals who are deaf-blind, but the Department has determined not to continue funding for DSAT. We agree that it is important for deaf consumers to understand their basic legal rights and be equipped with knowledge and confidence in order to effectively communicate their preferred accommodations and make appropriate requests as they transition from secondary education to post-secondary settings and competitive integrated employment. For this program, however, every specialty area project must be focused specifically on interpreting, which DSAT is not. We believe that funding the specialty areas described in this notice will provide interpreters with critically needed skills.

There are other vehicles funded by the Department that protect and advocate for individuals with disabilities, many of which teach self-advocacy skills. For example, the Client Assistance Program (CAP) is designed to advise and inform clients, client applicants, and other individuals with disabilities of all the available services and benefits under the Rehabilitation Act of 1973, as amended, and of the services and benefits available to them under Title I of the Americans with Disabilities Act (ADA). In addition, CAP grantees may assist and advocate for clients and client applicants about projects, programs, and services provided under the Rehabilitation Act. In providing assistance and advocacy under Title I of the Rehabilitation Act, a CAP agency may provide assistance and advocacy about services directly related to employment for the client or client applicant.

The Department also funds Parent Training and Information Centers (PTI centers) authorized under the Individuals with Disabilities Education Act (IDEA). Each State has at least one PTI center to provide training and information to students with disabilities and their families about their rights and services under IDEA. In addition, RSA currently funds seven State and regional PTI centers under section 303(c) of the Rehabilitation Act. All of these PTI centers provide training and information to enable individuals and their families to participate more effectively in meeting the vocational, independent living, and rehabilitation needs of such individuals.

Finally, the Centers for Independent Living authorized under title VII of the Rehabilitation Act and administered by the Department of Health and Human Services provide advocacy services for individuals with disabilities, and the modules developed on DSAT are among the tools they may use to teach deaf consumers to advocate for their rights. The existence of the programs described here, and their ability to use DSAT materials developed in previous grant cycles make it less necessary to continue to support DSAT through this competition.

We also believe that there is sufficient demand in the market for DSAT to sustain the curriculum without Federal investment. Since the DSAT curriculum was unveiled in 2010, more than 2,000 deaf, hard of hearing, and deaf-blind consumers have attended a DSAT consumer training and more than 250 deaf, hard of hearing, and deaf-blind individuals have been trained as DSAT trainers. In 2013, the DSAT curriculum was expanded to include deaf-blind-specific adaptations, and 10 deaf-blind individuals undertook a rigorous four-day deaf-blind self advocacy training (DBSAT) train the trainer course in preparation to provide future DBSAT to their peers.

We agree that the DSAT curriculum fills a significant gap experienced by educators, VR counselors, and community agency personnel, such as staff from centers for independent living and community rehabilitation programs. For example, as part of the Postsecondary Educational Programs Network (pepnet 2) Building State Capacity Summit, the team from Georgia recognized the value of the training materials and focused their five-year plan on improving self-advocacy and self-determination skills among deaf and hard of hearing high school and middle school students across the State. After piloting the project, they have worked closely with DSAT trainers to ensure that the curriculum addressed the needs of the population served. We expect that these and other strategies for using the existing DSAT materials will grow.

Change: None.

Comment: One commenter stated that the proposed priority is unnecessarily narrow and restrictive; needs greater input from more perspectives, especially those of the deaf communities to be served by the funding; and should embrace creativity and innovation. The commenter maintained that, while the emphasis on evidence and data that the proposed priority encourages is important, more evidence to support the proposed priority would have been useful as well.

Discussion: We do not agree that the priority is narrow or restrictive. However, we agree that creativity, innovation, and input from multiple perspectives are important for this program. Accordingly, in addition to the specialty areas the Department specified in this priority, we are also seeking field-initiated projects. While only one report was cited as support in the background section of the notice of proposed priority for this program, we acknowledge there are other works of research in the field of interpreter training that are equally valid. Therefore, for each area of specialty training, applicants may consult and incorporate relevant studies and evidence into their proposals.

Change: None.

Eligibility Requirements

Comments: A few commenters recommended the Department change the requirement in the priority that prevents applicants from submitting different proposals under more than one specialty area.

Another commenter asked whether an application may focus on multiple specialty areas, such as dysfluent language competencies and trilingual interpreting. For example, the commenter stated that for many deaf refugees in the United States, ASL is their first readily accessible language, and it becomes their primary communication choice despite their recent acquisition of this language. These individuals could benefit from interpreters who trained as trilingual interpreters and are familiar with working with dysfluent individuals.

Discussion: We agree that applicants should be able to submit different proposals for different specialty areas. However, the proposed components of the project (*i.e.,* the competencies working interpreters must demonstrate in order to provide high-quality services in the identified specialty area, as well as the design, delivery of training, and evaluation) must be tailored to the specific specialty area. Applications proposing the same content for multiple specialty areas will not be considered.

We also agree that applicants may submit proposals that focus on more than one specialty area. We regard these combined proposals as field-initiated topics that should be submitted under Specialty Area 3.

However, as to the comment suggesting combining dysfluent language competencies and trilingual interpreting, we believe applicants could include trilingual interpreting as a secondary focus for working interpreters along with training in dysfluent language competencies. Applications for this combination should still be submitted under Specialty Area 1.

Changes: We revised the specialty areas that immediately follow the application requirements in the priority in order to allow applicants to submit different proposals under more than one specialty area and to allow applicants to submit proposals that combine areas of specialty training. We added language directing proposals combining areas of specialty training to be submitted under Specialty Area 3: Field-initiated topics.

Under Specialty Area 1, we added language allowing applicants to include trilingual interpreting as a secondary focus for working interpreters who may require both training as trilingual interpreters and gaining familiarity working with dysfluent individuals.

Comment: One commenter recommended removing the proposed eligibility requirement for applicants under "Specialty Area 3: Field-initiated topics" in order to allow topics focused on interpreting for pre-K to grade 12 students. The commenter suggested that one way to address the increase in providing services to deaf individuals with idiosyncratic and dysfluent language is to ensure that educational interpreters working in pre-K to grade 12 have the training and supports they need to effectively serve students.

Discussion: Programs that prepare working interpreters to work in pre-K to grade 12 are not eligible because the focus of this program is to prepare interpreters to work in VR settings. To that end, we chose to limit eligible applicants to those programs that provide training to interpreters in such settings. We acknowledge there is emphasis in the Workforce Innovation and Opportunity Act (WIOA) on providing services and support to transition-age youth. However, the Department has other resources to support programs preparing pre-K to grade 12 personnel. For example, the Department currently funds grant awards under the IDEA Personnel Preparation in Special Education, Early Intervention, and Related Services program to improve the quality and increase the number of personnel who are fully credentialed to serve children, including infants and toddlers, with disabilities, especially in areas of chronic personnel shortage, by supporting projects that prepare special education, early intervention, and related services personnel at the baccalaureate, master's, and specialist levels. More specifically, this program funds a specialty area to serve school-age children with low incidence disabilities by training personnel who serve children with low incidence disabilities, such as visual impairments, hearing impairments, and simultaneous visual and hearing impairments. Projects preparing educational interpreters are eligible under this focus area. For these reasons, we have chosen to limit applicants under this competition to those who train interpreters to work in VR settings.

Change: None.

Comments: Several commenters noted that the priority does not specify entities eligible to apply for funds, such as associate of the arts (AA) programs, associate in applied sciences (AAS) programs, baccalaureate degree ASL-English programs accredited by the Commission on Collegiate Interpreter Education (CCIE), and non-CCIE-accredited baccalaureate degree ASL-English programs. Many commenters recommended that eligible applicants be degree-granting institutions with a demonstrated track record of relationships with relevant stakeholders such as the National Association of the Deaf, Registry of Interpreters for the Deaf, Conference of Interpreter Trainings, and others, as appropriate.

Discussion: Under the statute authorizing this program (section 302(f)(1)(A) of the Rehabilitation Act of 1973, as amended), eligible applicants are States and public or nonprofit agencies and organizations, including American Indian tribes and institutions of higher education, which includes CCIE-accredited and non-CCIE-accredited baccalaureate degree ASL-English programs. We do not believe further clarification in the priority is needed.

As a technical matter, AA/AAS programs are eligible, but the focus of this program is to prepare working interpreters to work in VR settings. To that end, in order to be eligible, applicants must be able to provide training to working interpreters in such settings, and such applicants would typically be institutions granting baccalaureate degrees.

Change: None.

Working Interpreter

Comments: Several commenters recommended expanding the proposed definition of "working interpreter." One commenter noted that there may be a number of certified, qualified deaf interpreters who would otherwise be successful participants but do not possess a baccalaureate degree in ASL-English interpretation. Other commenters recommended aligning the definition of "working interpreter" with requirements established by the Registry of Interpreters for the Deaf (RID). One commenter indicated RID requires interpreters to possess a baccalaureate degree in order to be eligible for generalist certification, with certain limited exceptions. RID does not currently specify the type of degree a candidate must possess but instead recognizes that any baccalaureate degree represents a liberal arts education that sets a strong foundation of critical thinking and broad world view. Therefore, this commenter suggested the Department create an equivalency determination when the degree requirement would unnecessarily exclude underrepresented populations.

For example, the commenter stated that equivalent alternative criteria that could be allowable in lieu of the educational requirements might include life experience, years of professional experience, and years of education (credit hours) not totaling a formal degree. The commenter noted that RID also accepts continuing education credits in addition to these other requirements in order to satisfy the educational equivalency requirements.

Discussion: We agree that we should expand the definition of "working interpreter" to more closely align with RID requirements. This will avoid unnecessarily limiting the pool of qualified participants and promote participation within projects.

Change: We amended the definition of "working interpreter" in the first paragraph of the final priority to include interpreters with a baccalaureate degree in ASL-English who possess a minimum of three years of relevant experience as an interpreter or equivalence such as relevant professional experience and years of education (credit hours) not equivalent to a formal degree.

Credentials and Certifications

Comments: Some commenters indicated that the priority does not mention credentials that participants must achieve upon successful completion of the training program. One commenter recommended the Department consider other available national-level credentials that are equivalent to credentials awarded by the RID. Another commenter suggested the Department consider State-level certification or licensure, such as the Board for Evaluation of Interpreters (BEI), for certification or licensure to offer interpreting services within the State. One commenter noted that the BEI testing options include basic, advanced, and master's level certification tests, as well as testing in legal interpreting, trilingual interpreting, a certified deaf interpreter test, and a soon-to-be-released medical interpreting test.

Discussion: The priority does not designate a specific certification as a desired outcome for this program, nor does it require participants to achieve a designated certification upon successful completion in the program. However, applicants may choose to award continuing education credits or college or master's level credits to participants in the training program and we encourage applicants to consider doing so.

We believe there is limited information available on the reliability and validity of assessments used by States to confer certifications and licensures. For example, in some cases, an individual pays a fee to receive a license to work as an interpreter in a State, regardless of skill or competency. In other cases, assessments, such as the BEI, are State specific, and there is no information about how the specific levels of skills and competencies they assess compare with the level of skills and competencies required to pass other State-level licensure tests.

Applicants may use national and State-level licensures and certifications, as applicable, to assess participant progress in competency and skill level. Any proposed instruments must be valid and reliable and the applicant must submit a rationale to support the use of each instrument. However, the Department does not consider it appropriate at this time to require all applicants to adopt specific national or State-level certifications or licensures.

Change: None.

Comment: One commenter stated that the priority requires trainers to be certified or recognized in the specialty area of training, but does not believe there is enough data to determine whether there are enough trainers in specialty areas to meet this requirement.

The commenter also does not believe there is data to indicate whether a sufficiently large pool of working interpreters that possess baccalaureate degrees in ASL-English and three years of interpreting experience who also possess competence in the proposed specialty training areas.

This commenter recommended the Department include flexibility on the qualifications of trainers, as well in the definition of "working interpreter."

Discussion: We believe the priority provides sufficient flexibility on the qualifications of trainers. Under paragraph (b)(2) of the requirements for this program, applicants may identify and partner with trainers who are either certified or recognized in the specialty area through formal or informal certification. If certification is not available in the specialty area, applicants may provide evidence of relevant training and experience (*e.g.*, provide a portfolio that includes training verification, video samples, letters of support from consumers and employers, etc.).

As stated earlier, we have also amended the definition of "working interpreter" to include interpreters with a baccalaureate degree in ASL-English who possess a minimum of three years of relevant experience as an interpreter or equivalence such as relevant professional experience, and years of education (credit hours) not totaling a formal degree.

Change: None.

Project Requirements

Comment: One commenter asked the Department to clarify the baseline numbers against which "increased" numbers will be measured for project outcomes (*i.e.* an increase in the number of interpreters who are trained to work with deaf consumers who require specialized interpreting and an increase in the number of interpreters trained in specialty areas who obtain or advance in employment in the areas for which they were prepared).

Discussion: We intend for applicants to provide baseline data in their applications for the actual or estimated number of working interpreters currently trained in a specialty area. We acknowledge that baseline numbers may not be available to applicants proposing to develop training in topics that address new specialty areas. In those cases, we will accept zero as a baseline, provided that the applicants adequately explain the lack of data to establish a baseline. We also expect applicants to provide a target number of new working interpreters that will be trained in a specialty area.

Change: We added a new paragraph (a)(2) to the requirements to clarify baseline and target data that must be included in the application.

Comments: One commenter recommended that the Department clarify the purpose of the coordination and communication requirement in paragraph (c)(10)(iv)(B). For example, one commenter asked if this requirement allows applicants to interact with specific projects funded by the Department, such as the IDEA Personnel Development to Improve Services and Results for Children with Disabilities Program, which can support projects focused on K–12 interpreting.

One commenter recommended interaction with other Department-funded projects and stated that dysfluent language evident in deaf adults can be traced, in part, to inadequate language models early in life. According to this commenter, coordination of interpreter education efforts between children and adults could be a key step to addressing dysfluency among future Deaf generations.

Discussion: We intended for the language in requirement (c)(10)(iv)(B) to mean that grantees would communicate, coordinate, and collaborate with other Department-funded projects for the purposes of exchanging relevant information such as outcome data and promising practices, as well as disseminating training material and products developed under this program. Applicants may also communicate, coordinate, and collaborate with other Department-funded projects for the purposes of informing, improving, and strengthening training developed under this program. The priority does not require formal relationships (*e.g.*, memoranda of understanding) with other Department-funded projects.

We will not further specify how this communication, collaboration, or coordination will occur because we believe applicants are well suited to make this determination.

Change: None.

Comment: One commenter asked for clarification of the second paragraph under the proposed priority concerning whether pre-service training is an allowable project activity. The commenter suggested the Department consider allowing the development of content for pre-service training because it could have a positive long-term impact on the quality of interpreting.

Discussion: Pre-service training is not the focus of this priority. The priority states that applicants may develop a new training program or stand-alone modules that could also be incorporated into an existing baccalaureate degree ASL-English program. Applicants are expected to develop and deliver training of sufficient scope, intensity, and duration for working interpreters to achieve increased skill, knowledge, and competence in a specialty area. However, applicants may consider a variety of resources (such as available pre-service training material) that may inform, support, or strengthen the development of training for English-ASL interpreter training in specialized areas. As a result of new training curricula established through this program, pre-service training modules could be developed as a "feeder" into existing baccalaureate degree ASL-English programs.

Change: None.

Comment: One commenter suggested that project timelines be proposed, but not required, in the priority. The commenter reasoned that the requirement to develop training materials and curricula in a single year and then implement them over the following four years is not unreasonable but noted that, with a focus on new specialty training areas, a complete curriculum could require two or more years to develop. The commenter also recommended that the timeline in each application be reviewed on its own merits. For example, an application to address training in a new specialty area may require more time, funding, and extended collaboration to fully develop a curriculum. On the other hand, an application that demonstrates the intention of building on, enhancing, or significantly revising a previously developed curriculum might be completed more quickly.

Discussion: We agree that an application to address training in a new specialty area may require more time to fully develop a curriculum. Therefore, if applicants determine additional time may be necessary to fully develop a curriculum and obtain input and feedback from key partners, relevant stakeholders, and consumers, they must provide adequate justification in their application.

Change: In the final priority we have added that applicants must provide adequate justification in their application if they determine additional time may be necessary to fully develop a curriculum and obtain input and feedback from key partners, relevant stakeholders, and consumers.

Administration of the Grants

Comment: One commenter suggested the Department award these projects as cooperative agreements rather than grants. Another commenter stated that implementing a cooperative agreement for this funding would be a positive strategy to monitor quality and achievement of proposed goals. This commenter further stated that providing transparent decision-making by RSA, with open and explicit rationales for funding choices and re-funding choices, is needed in order to insure that an evaluation is effectively conducted and that funds are awarded (or withheld) based on evidence of effective program management. This commenter urged the Department to require transparent reporting by, and evaluation of, the grantee that is easily and quickly accessible and that encourages public input at every evaluation point, in order to help insure that such evaluation is incorporated and integrated throughout.

Discussion: The priority does not specify whether these projects would be awarded as cooperative agreements. The Department has flexibility to make this determination, and we will announce that decision in the notice inviting applications. As to the commenter's recommendation that the Department involve the public in reporting by grantees and evaluation of the projects, the Department already has established processes and procedures for monitoring project performance. Further, the Notice Inviting Applications will specify annual and final reporting requirements and performance measures.

The Department is committed to transparency and will make available to the public abstracts of successful applications. Products produced as a result of these grants will be made available to the public through the National Clearinghouse of Rehabilitation Training Materials.

Change: None.

Final Priority: This notice contains one final priority.

Interpreter Training in Specialty Areas.

Final Priority: The purpose of this priority is to fund projects that provide training for English-American Sign Language (ASL) interpreter training in specialty areas. The training must be provided to working interpreters (*e.g.,* interpreters with a baccalaureate degree in ASL-English who possess a minimum of three years of relevant experience as an interpreter or equivalence such as relevant professional experience, and years of education (credit hours) not totaling a formal degree) who need to develop a new skill area or enhance an existing skill area. Within this final priority, the Assistant Secretary intends to fund training in the following specialty areas: (1) Interpreting for consumers with dysfluent language competencies (*e.g.,* individuals who use idiosyncratic signs or display limited first language competency in either spoken or sign language, due to delayed acquisition of the first language); (2) trilingual interpreting (*e.g.,* language fluency in first, second, and third languages with one of the three languages being ASL); and (3) field-initiated topics.

During the project, applicants must develop and deliver training of sufficient scope, intensity, and duration for working interpreters to achieve increased skill, knowledge, and competence in a specialty area. Applicants may develop a new training program or stand-alone modules that could also be incorporated into an existing baccalaureate degree ASL-English program. The training program or modules must be developed by the end of the first year of the project period and delivered in years two, three, four, and five of the project period. Applicants must provide adequate justification in their application if they determine additional time may be necessary to fully develop a curriculum and obtain input and feedback from key partners, relevant stakeholders, and consumers.

The projects must be designed to achieve, at a minimum, the following outcomes:

(a) An increase in the number of interpreters who are trained to work with deaf consumers who require specialized interpreting; and

(b) An increase in the number of interpreters trained in specialty areas who obtain or advance in employment in the areas for which they were prepared.

To be considered for funding, applicants must meet the requirements contained in this final priority, which are as follows:

(a) Demonstrate, in the narrative section of the application under "Significance of the Project," how the proposed project will address the need for sign language interpreters in a specialty area. To address this requirement, applicants must:

(1) Present applicable data demonstrating the need for interpreters in the specialty area for which training will be developed by the project in at least three distinct, noncontiguous geographic areas, which may include the U.S. Territories;

(2) Present baseline data for the number or estimated number of working interpreters currently trained in a specialty area. In the event that an applicant proposes training in a new specialty area that does not currently exist or for which there are no baseline data, the applicant should provide an adequate explanation of the lack of reliable data and may report zero as a baseline;

(3) Explain how the project will increase the number of working interpreters in a specialty area who demonstrate the necessary competencies to meet the communication needs of individuals who are deaf, hard of hearing, or deaf-blind. To meet this requirement, the applicant must—

(i) Identify competencies that working interpreters must demonstrate in order to provide high-quality services in the identified specialty area using practices that are promising or based on instruction supported by evidence and intervention, when available; and

(ii) Demonstrate that the identified competencies are based on practices that are promising or supported by evidence that will result in effectively meeting the communication needs of individuals who are deaf, hard of hearing, or deaf-blind.

(b) Demonstrate, in the narrative section of the application under "Quality of Project Design," how the proposed project will—

(1) Provide training in person or remotely to at least three distinct, noncontiguous geographic areas identified in paragraph (a)(1);

(2) Identify and partner with trainers who are certified and recognized in the specialty area through formal or informal certification to develop and deliver the training. If certification is not available in the specialty area, provide evidence of relevant training and experience (*e.g.*, provide a portfolio that includes training verification, video samples, letters of support from consumers and employers, etc.);

(3) Be based on current research and make use of practices that are promising or supported by evidence. To meet this requirement, the applicant must describe—

(i) How the proposed project will incorporate current research and practices that are promising or supported by evidence in the development and delivery of its products and services;

(ii) How the proposed project will engage working interpreters with different learning styles; and

(iii) How the proposed project will ensure that working interpreters interact with deaf individuals who have a range of communication skills, from those with limited language skills to those with high-level, professional language skills.

(c) In the narrative section of the application under "Quality of Project Services," the applicant must—

(1) Demonstrate how the project will ensure equal access and treatment for eligible project participants who are members of groups who have traditionally been underrepresented based on race, color, national origin, gender, age, or disability;

(2) Describe the criteria that will be used to identify high-quality applicants for participation in the program, including any pre-assessments that may be used to determine the skill, knowledge base, and competence of the working interpreter;

(3) Describe the recruitment strategies the project will use to attract high-quality working interpreters, including specific strategies targeting high-quality participants from traditionally underrepresented groups (*e.g.*, individuals with disabilities and individuals living in remote areas);

(4) Describe how the project will ensure that all training activities and materials are fully accessible;

(5) Describe the approach that will be used to enable more working interpreters to participate in and successfully complete the training program, specifically participants who need to work while in the program, have child care or elder care considerations, or live in geographically isolated areas. The approach must emphasize innovative instructional delivery methods, such as distance learning or block scheduling (a type of academic scheduling that offers students fewer classes per day for longer periods of time), which would allow working interpreters to more easily participate in the program;

(6) Describe the approach that will be used to enable working interpreters to successfully complete the program or stand-alone modules, to include mentoring, monitoring, and accommodation support services;

(7) Describe how the project will incorporate practices that are promising and supported by evidence for adult learners;

(8) Demonstrate how the project is of sufficient scope, intensity, and duration to adequately prepare working interpreters in the identified specialty area of training. To address this requirement, the applicant must describe how—

(i) The components of the proposed project will support working interpreters' acquisition and enhancement of the competencies identified in paragraph (a)(2)(i);

(ii) The components of the project will allow working interpreters to apply their content knowledge in a practical setting;

(iii) The proposed project will provide working interpreters with ongoing guidance and feedback; and

(iv) The proposed project will provide ongoing induction opportunities and support working interpreters after completion of the specialty area program.

(9) Demonstrate how the proposed project will actively engage representation from consumers, consumer organizations, and service providers, especially vocational rehabilitation (VR) agencies, interpreters, interpreter training programs, and individuals who are deaf and deaf-blind in the project, including project development, design, implementation, delivery of training, dissemination, sustainability planning, program evaluation, and other relevant areas as determined by the applicant;

(10) Describe how the project will conduct dissemination and coordination activities. To meet this requirement, the applicant must—

(i) Describe its plan for disseminating information to and coordinating with VR agencies, American Job Centers and other workforce partners regarding finding interpreters with the specialized interpreting skills needed; disseminating information to working interpreters about training available in the specialty area, and broadly disseminating successful strategies for preparing working interpreters in a specialty area;

(ii) Describe its strategy for disseminating products developed during the project period. To meet this requirement the applicant must—

(A) Develop and maintain a state-of-the-art archiving and dissemination system that is open and available to the public and provides a central location for later use of training materials, including curricula, audiovisual materials, Webinars, examples of emerging and promising practices, and any other relevant material;

(B) Provide a minimum of three Webinars or video conferences over the course of the project. Applicants may determine the audience, content, and goals of this activity. For instance, applicants may consider disseminating information to working interpreters not enrolled in the program about training in a specialty area, as well as interacting with interpreter educators about the curriculum or training module design, challenges, solutions, and results achieved.

Note: All products produced by the grantees must meet government- and industry-recognized standards for accessibility, including section 508 of the Rehabilitation Act.

(iii) Describe its approach for incorporating the use of information technology (IT) into all aspects of the project. The approach must include establishing and maintaining a state-of-the-art IT platform that is sufficient to support Webinars, teleconferences, video conferences, and other virtual methods of dissemination of information.

Note: In meeting the requirements mentioned in paragraphs (c)(10)(ii)(A) and

(B) and (c)(10)(iii) above, projects may either develop new platforms or systems or may modify existing platforms or systems, so long as the requirements of this priority are met.

(iv) Describe its approach for conducting coordination and collaboration activities. To meet this requirement, the applicant must—

(A) Establish a community of practice[3] in the specialty area of training that focuses on project activities in this priority and acts as a vehicle for communication and exchange of information among participants in the program and other relevant stakeholders;

(B) Communicate, collaborate, and coordinate with other relevant Department-funded projects, as applicable;

(C) Maintain ongoing communication with the RSA project officer and other RSA staff as required; and

(D) Communicate, collaborate, and coordinate, as appropriate, with key staff in State VR agencies, such as the State Coordinators for the Deaf; State and local partner programs; consumer organizations and associations, including those that represent individuals who are deaf, hard of hearing, deaf-blind, and late deafened; and relevant RSA partner organizations and associations.

(d) In the narrative section of the application under "Quality of the Evaluation Plan," include an evaluation plan for the project. To address this requirement, the evaluation plan must describe—

(1) An approach, using pre- and post-assessments, for assessing the level of knowledge, skills, and competencies gained among participants;

(2) An approach for assessing the application of knowledge, skills, and competencies after completion; and

(3) An approach for incorporating oral and written feedback from trainers, from deaf consumers, and any feedback from mentoring sessions conducted with the participants;

(4) Evaluation methodologies, including instruments, data collection methods, and analyses that will be used to evaluate the project;

(5) Measures of progress in implementation, including the extent to which the project's activities and products have reached their target populations; intended outcomes or results of the project's activities in order to evaluate those activities; and how well the goals and objectives of the proposed project, as described in its logic model,[4] have been met;

(6) How the evaluation plan will be implemented and revised, as needed, during the project. The applicant must designate at least one individual with sufficient dedicated time, experience in evaluation, and knowledge of the project to coordinate the design and implementation of the evaluation. For example, coordination with any identified partners in the application and RSA to make revisions post award to the logic model in order to reflect any changes or clarifications to the model and to the evaluation design and instrumentation with the logic model (*e.g.,* designing instruments and developing quantitative or qualitative data collections that permit collecting of progress data and assessing project outcomes);

(7) The standards and targets for determining effectiveness of the project;

(8) How evaluation results will be used to examine the effectiveness of implementation and the progress toward achieving the intended outcomes; and

(9) How the methods of evaluation will produce quantitative and qualitative data that demonstrate whether the project activities achieved their intended outcomes.

(e) Demonstrate, in the narrative section of the application under "Adequacy of Project Resources," how—

(1) The proposed project will encourage applications for employment with the project from persons who are members of groups that have historically been underrepresented based on race, color, national origin, gender, age, or disability;

(2) The proposed project personnel, consultants, and subcontractors have the qualifications and experience to provide training to working interpreters and to achieve the project's intended outcomes;

(3) The applicant and any identified partners have adequate resources to carry out the proposed activities; and

(4) The proposed costs are reasonable in relation to the anticipated results and benefits;

(f) Demonstrate, in the narrative section of the application under "Quality of the Management Plan," how—

(1) The proposed management plan will ensure that the project's intended outcomes will be achieved on time and within budget. To address this requirement, the applicant must describe—

(i) Clearly defined responsibilities for key project personnel, consultants, and subcontractors, as applicable; and

(ii) Timelines and milestones for accomplishing the project tasks.

(2) Key project personnel and any consultants and subcontractors will be allocated to the project and how these allocations are appropriate and adequate to achieve the project's intended outcomes, including an assurance that such personnel will have adequate availability to ensure timely communications with stakeholders and RSA;

(3) The proposed management plan will ensure that the products and services provided are of high quality; and

(4) The proposed project will benefit from a diversity of perspectives, especially relevant partners, groups, and organizations described throughout this notice, in its development and operation.

(g) Address the following application requirements. The applicant must—

(1) Include, in Appendix A, a logic model that depicts, at a minimum, the goals, activities, outputs, and intended outcomes of the proposed project;

(2) Include, in Appendix A, person-loading charts and timelines, as applicable, to illustrate the management plan described in the narrative; and

(3) Include, in the budget, attendance at a one-day intensive review meeting in Washington, DC, during the third quarter of the third year of the project period.

Specialty Areas

With this final priority, the Secretary intends to fund four national projects in the following specialty areas: (1) Interpreting for consumers with dysfluent language competencies (*e.g.,* individuals who use idiosyncratic signs or display limited first language competency in either spoken or sign language, due to delayed acquisition of the first language); (2) trilingual interpreting (*e.g.,* language fluency in first, second, and third languages with one of the three languages being ASL); and (3) field-initiated topics. Applicants must identify the specific focus area (1, 2, or 3) under which they are applying as part of the competition title on the application cover sheet (SF form 424, line 4).

Applicants may submit proposals under one or more specialty area.

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[3] A community of practice (CoP) is a group of people who work together to solve a persistent problem or to improve practice in an area that is important to them and who deepen their knowledge and expertise by interacting on an ongoing basis. CoPs exist in many forms, some large in scale that deal with complex problems, others small in scale that focus on a problem at a very specific level. For more information on communities of practice, see: *www.tadnet.org/pages/510.*

[4] A logic model communicates how the project will achieve its intended outcomes and provides a framework for both the formative and summative evaluations of the project.

Applications proposing the same content for different specialty areas will not be considered.

Applicants may combine more than one specialty and these applications must be submitted under Specialty Area 3: Field-initiated topics.

Specialty Area 1: Interpreting for Consumers With Dysfluent Language Competencies

Interpreting for deaf and hard of hearing, and deaf-blind consumers with dysfluent language competencies include: (1) Those with limited, idiosyncratic, or differing levels of first and second language fluency in English and ASL); (2) those who have families using non-English spoken languages at home and have limited or no fluency in English and ASL; and (3) those with cognitive and physical disabilities that impact linguistic competencies. Under this specialty area, applicants may include trilingual interpreting as a secondary focus for working interpreters who may require both training as trilingual interpreters and gaining familiarity working with dysfluent individuals.

Specialty Area 2: Trilingual Interpreting

Trilingual interpreting is interpreting between three different languages; that is, two spoken languages such as English and Spanish, and ASL. This requires a working interpreter to be competent in three different languages and seamlessly facilitate communication between those languages in real time. RSA is seeking to fund similar projects in trilingual interpreting that includes languages that may be spoken in the United States. Applications may address multiple language combinations. In this instance, applicants must propose a framework that will be used to provide trilingual interpreter training. Applicants must develop separate modules for each language and ensure the training content appropriately addresses the cultural nuances of the language.

Applicants that choose to focus on trilingual interpreting in English/Spanish/ASL must propose to improve, update, and develop new material to support existing specialty training in this area. Applicants must describe in their application specific improvements, updates, and new material to be developed and provide rationale for why this is needed. Applicants must provide evidence to support the demand for trilingual interpreters in English/Spanish/ASL and, to the extent possible, specify areas of the country in which there are not enough trilingual English/Spanish/ASL interpreters to adequate meet the communication needs of Deaf, hard-of-hearing, and Deaf-blind consumers.

Trilingual interpreting in English/Spanish/ASL that proposes only to continue existing training developed during the 2010–2016 grant cycle or earlier cycles is *not* eligible under this priority.

Specialty Area 3: Field-Initiated Topics

Field-initiated topics that address the needs of working interpreters to acquire specialized knowledge and competencies. These topics may address new specialty areas that require development of training modules of sufficient intensity, duration, and scope of sequence to warrant funding of an entire grant. Proposed topics may also replace training in an established specialty area that is no longer relevant. For instance, applicants may propose new or updated training, such as interpreting in a VR setting given reauthorization of the Rehabilitation Act, as amended, by WIOA. Applicants may also propose new subsets of training in established specialty areas. For instance, in health care interpreting, mental health might be one permissible subset of training because it has its own unique challenges and complexities in terms of setting and deaf consumer needs. In addition, applicants must provide sufficient evidence to demonstrate the need for the proposed new specialty training project or to show that an existing specialty training project is not adequately meeting the training needs of interpreters in order to better meet the linguistic and communication needs of deaf, hard-of-hearing, and deaf-blind consumers.

Applicants may also propose to enhance existing training developed in prior grant cycles for deaf-blind interpreting, health care interpreting, legal interpreting, interpreting in a VR setting, interpreting provided by Deaf interpreters, and video remote interpreting and video relay interpreting. In this instance, applicants must propose to improve, update, and develop new material to support existing specialty training in these areas. Applicants must describe in their application specific improvements, updates, and new material to be developed and provide rationale for why this is needed. Applicants must demonstrate the demand for interpreters in these existing specialty areas and, to the extent possible, specify areas of the country in which there are not enough trained interpreters to adequately meet the communication needs of deaf, hard-of-hearing, and deaf-blind consumers.

Applications that propose only to continue existing training in these areas are not eligible for funding. Additional field-initiated topics not eligible under this final priority include topics focusing on educational interpreting for pre-k-12 and deaf self-advocacy training.

Note: The Secretary intends to fund a total of four projects in FY 2016 that have been awarded at least eighty-percent of the maximum possible points, including at least one project from each of the three specialty areas. As a result, the Secretary may fund applications out of rank order.

Types of Priorities:

When inviting applications for a competition using one or more priorities, we designate the type of each priority as absolute, competitive preference, or invitational through a notice in the **Federal Register**. The effect of each type of priority follows:

Absolute priority: Under an absolute priority, we consider only applications that meet the priority (34 CFR 75.105(c)(3)).

Competitive preference priority: Under a competitive preference priority, we give competitive preference to an application by (1) awarding additional points, depending on the extent to which the application meets the priority (34 CFR 75.105(c)(2)(i)); or (2) selecting an application that meets the priority over an application of comparable merit that does not meet the priority (34 CFR 75.105(c)(2)(ii)).

Invitational priority: Under an invitational priority, we are particularly interested in applications that meet the priority. However, we do not give an application that meets the priority a preference over other applications (34 CFR 75.105(c)(1)).

This notice does not preclude us from proposing additional priorities, requirements, definitions, or selection criteria, subject to meeting applicable rulemaking requirements.

Note: This notice does *not* solicit applications. In any year in which we choose to use this priority, we invite applications through a notice in the **Federal Register**.

Paperwork Reduction Act of 1995

As part of its continuing effort to reduce paperwork and respondent burden, the Department provides the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This helps ensure that: the public understands the Department's collection instructions, respondents can provide the requested data in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the Department can properly assess the impact of collection requirements on respondents.

This final priority contains information collection requirements that are approved by OMB under the National Interpreter Education program 1820–0018; this final priority does not affect the currently approved data collection.

Executive Orders 12866 and 13563

Regulatory Impact Analysis

Under Executive Order 12866, the Secretary must determine whether this regulatory action is "significant" and, therefore, subject to the requirements of the Executive order and subject to review by the Office of Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of $100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities in a material way (also referred to as an "economically significant" rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles stated in the Executive order.

This final regulatory action is not a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866.

We have also reviewed this final regulatory action under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only upon a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency "to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible." The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include "identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes."

We are issuing this final priority only on a reasoned determination that its benefits justify its costs. In choosing among alternative regulatory approaches, we selected those approaches that maximize net benefits. Based on the analysis that follows, the Department believes that this regulatory action is consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action does not unduly interfere with State, local, and tribal governments in the exercise of their governmental functions.

In accordance with both Executive orders, the Department has assessed the potential costs and benefits, both quantitative and qualitative, of this regulatory action. The potential costs are those resulting from statutory requirements and those we have determined as necessary for administering the Department's programs and activities.

Through this priority, training will be provided to working interpreters for English-ASL interpreter training in specialty areas. These activities will help interpreters to more effectively meet the communication needs of individuals who are deaf or hard of hearing and individuals who are Deaf-blind. The training ultimately will improve the quality of VR services and the competitive integrated employment outcomes achieved by individuals with disabilities. This priority will promote the efficient and effective use of Federal funds.

Intergovernmental Review: This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides early notification of our specific plans and actions for this program.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT.**

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site, you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: August 9, 2016.

Sue Swenson,

Acting Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2016–19273 Filed 8–11–16; 8:45 am]

BILLING CODE 4000–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2012–0959; FRL–9948–11–Region 9]

Revisions to the California State Implementation Plan, Sacramento Metropolitan Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is finalizing a partial approval and partial disapproval of revisions to the Sacramento Metropolitan Air Quality Management District (SMAQMD or District) portion of the California State Implementation Plan (SIP). This action was proposed in the **Federal Register** on January 15, 2016 and concerns the District's demonstration regarding Reasonably Available Control Technology (RACT) requirements for the 1997 8-hour ozone National Ambient Air Quality Standard (NAAQS). Under authority of the Clean Air Act (CAA or the Act), this action directs California to correct RACT deficiencies in the SMAQMD portion of the California SIP.

DATES: This rule is effective on September 30, 2016.

ADDRESSES: The EPA has established docket number[1] EPA–R09–OAR–2012–0959 for this action. Generally, documents in the docket for this action are available electronically at *www.regulations.gov* or in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California 94015–3901. While all documents in the docket are listed at *www.regulations.gov*, some information may be publicly available only at the hard copy location (*e.g.*, copyrighted material, large maps), and some may not be publicly available in either location (*e.g.*, Confidential Business Information (CBI)). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: James Shears, EPA Region IX, (213) 244–1810, *shears.james@epa.gov*.

SUPPLEMENTARY INFORMATION: Throughout this document, "we," "us" and "our" refer to the EPA.

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I. Proposed Action

On January 15, 2016 (81 FR 2136), the EPA proposed to partially approve and partially disapprove the following documents that were submitted for incorporation into the California SIP:

Local agency	Document	Adopted	Submitted
SMAQMD	Reasonably Available Control Technology (RACT) as Applicable to the 8-hour Ozone Standard, dated October 26, 2006 ("2006 RACT SIP").	10/26/06	7/11/07
SMAQMD	Reasonably Available Control Technology (RACT) Update as Applicable to the 8-Hour Ozone Standard, dated October 23, 2008 ("Updated RACT SIP").	10/23/08	1/21/09

We proposed to approve the 2006 RACT SIP and Updated RACT SIP with the exception of Rule 455, Pharmaceutical Manufacturing, and the municipal waste landfill category as satisfying the RACT requirements of CAA section 182(b)(2) and (f).

Also under CAA section 110(k)(3), we proposed to disapprove those elements of the 2006 RACT SIP and Updated RACT SIP that pertain to Rule 455 and the municipal waste landfill category because we found that these elements did not meet all of the applicable CAA requirements. In particular, we found that Rule 455, Pharmaceuticals Manufacturing, (amended 11/29/83 and 9/5/96) lacks test methods, recordkeeping, and monitoring requirements that are necessary to support enforcement of the rule. See CAA section 110(a). We also found that the California SIP did not contain any provisions to implement RACT for volatile organic compounds (VOCs) at the Kiefer landfill, which is a major source of VOCs located within the Sacramento Metro area.

SMAQMD's submittal also included a number of negative declarations. CAA Sections 182(b)(2) and (f) require that SIPs for ozone nonattainment areas classified as moderate or above implement RACT for any source covered by a Control Techniques Guidelines (CTG) document and any major stationary source of VOCs or nitrogen oxides (NO_X). If an ozone nonattainment area does not have any stationary sources covered by a particular CTG, then the area may submit a negative declaration certifying that there are no such sources in the relevant nonattainment area in lieu of adopting RACT requirements for that category. We proposed approval of SMAQMD's negative declarations because we determined that they complied with relevant CAA requirements.

Our proposed action contains more information on the basis for this rulemaking and on our evaluation of the 2006 RACT SIP and Updated RACT SIP.

II. Public Comments and EPA Responses

The EPA's proposed action provided a 30-day public comment period. During this period, we received no comments.

III. Final Action and CAA Consequences

A. Final Action

For the reasons provided in our January 15, 2016 proposed rule, the EPA is partially approving and partially disapproving SMAQMD's 2006 RACT SIP and Updated RACT SIP under CAA section 110(k)(3). In particular, we are approving all elements of the 2006 RACT SIP and Updated RACT SIP, with the exception of elements pertaining to Rule 455, Pharmaceutical Manufacturing, and the municipal waste landfill category, as satisfying the RACT requirements of CAA section 182(b)(2) and (f). We are disapproving those elements of the 2006 RACT SIP and Updated RACT SIP that pertain to Rule 455 and the municipal waste landfill category because we have determined that they do not meet all of the applicable CAA requirements.

B. CAA Consequences of Final Partial Disapproval

The EPA is committed to working with the District and CARB to resolve the identified RACT deficiencies. We note that SMAQMD will not be required to submit a revised CAA section 182 RACT SIP demonstration for the 1997 8-hour ozone NAAQS if it submits for SIP approval, rules and/or permit provisions that implement RACT for the pharmaceutical manufacturing source category, as well as RACT for VOCs for the Kiefer landfill, and the EPA fully approves them into the SIP. On April 28, 2016, SMAQMD repealed Rule 455 and adopted amendments to Rule 464, Organic Chemical Manufacturing Operations to incorporate the pharmaceutical manufacturing requirements from Rule 455 along with other improvements to implement RACT into Rule 464. SMAQMD plans, in July 2016, to adopt the relevant portions of the Kiefer landfill permit into the SIP to implement RACT.

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[1] Our proposal indicated that the docket number for this action was EPA–R09–2012–959. This final action corrects the docket number to "0959" to conform to numbering convention.

Because we are finalizing a partial disapproval of the 2006 RACT SIP and Updated RACT SIP, the EPA must promulgate a federal implementation plan (FIP) under section 110(c) unless we approve subsequent SIP revisions that correct the rule deficiencies within 24 months of the effective date of this action. In addition, sanctions will be imposed under CAA section 179 and 40 CFR 52.31, unless the EPA approves subsequent SIP revisions that correct the rule deficiencies or issues an interim final determination that submitted revisions correct the deficiencies within 18 months of the effective date of this action.

IV. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www2.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA because this action does not impose additional requirements beyond those imposed by state law.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities beyond those imposed by state law.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action does not impose additional requirements beyond those imposed by state law. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, will result from this action.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175, because the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction, and will not impose substantial direct costs on tribal governments or preempt tribal law. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not impose additional requirements beyond those imposed by state law.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

Section 12(d) of the NTTAA directs the EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. The EPA believes that this action is not subject to the requirements of section 12(d) of the NTTAA because application of those requirements would be inconsistent with the CAA.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Population

The EPA lacks the discretionary authority to address environmental justice in this rulemaking.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

L. Petitions for Judicial Review

Under CAA section 307(b)(1), petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 11, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: May 19, 2016.

Alexis Strauss,

Acting Regional Administrator, Region IX.

Part 52, Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraphs (c)(382)(ii)(C) and (c)(475) to read as follows:

§ 52.220 Identification of plan—in part.

* * * * *

(c) * * *

(382) * * *

(ii) * * *

(C) Sacramento Metropolitan Air Quality Management District.

(*1*) Reasonably Available Control Technology (RACT) as Applicable to the 8-Hour Ozone Standard, dated October 26, 2006, as adopted October 26, 2006, excluding the RACT determinations for:

(*i*) Pharmaceutical Products Manufacturing Source Category; and

(*ii*) Kiefer Landfill (RACT for volatile organic compounds).

* * * * *

(475) A new plan for the following AQMD was submitted January 21, 2009 by the Governor's designee.

(i) [Reserved]

(ii) Additional Material.

(A) Sacramento Metropolitan Air Quality Management District.

(*1*) Reasonably Available Control Technology (RACT) Update as Applicable to the 8-Hour Ozone Standard, dated October 23, 2008, adopted October 23, 2008.

* * * * *

■ 3. Section 52.222 is amended by adding paragraph (a)(2)(iv) to read as follows:

§ 52.222 Negative declarations.

(a) * * *

(2) * * *

(iv) *Negative declarations for Sacramento Metropolitan Air Quality Management District.*

CTG Source category	Negative declaration—CTG reference document	Submitted 7/11/07, adopted 10/26/06	Updated submitted 1/21/09, adopted 10/23/08
Aerospace Coating	EPA–453/R–97–004 and 59 FR 29216 (6/06/94)—Control of Volatile Organic Compound Emissions from Coating Operations at Aerospace Manufacturing and Rework Operations.		X
Automobile Coating	EPA–450/2–77–008—Control of Volatile Organic Emissions from Existing Stationary Sources, Volume II: Surface Coating of Cans, Coils, Paper, Fabrics, Automobiles, and Light-Duty Trucks.	X	
Dry Cleaning (Petroleum Solvent)	EPA–450/3–82–009—Control of Volatile Organic Compound Emissions from Large Petroleum Dry Cleaners.	X	
Graphic Arts (Rotogravure)	EPA–450/2–78–033—Control of Volatile Organic Emissions from Existing Stationary Sources, Volume VIII: Graphic Arts–Rotogravure and Flexography.		X
Large Appliance Coating	EPA–450/2–77–034—Control of Volatile Organic Emissions from Existing Stationary Sources, Volume V: Surface Coating of Large Appliances.	X	
Large Appliance Coating	EPA–453/R–07–004—Control Techniques Guidelines for Large Appliance Coatings.		X
Magnetic Wire Coating	EPA–450/2–77–033—Control of Volatile Organic Emissions from Existing Stationary Sources, Volume IV: Surface Coating for Insulation of Magnetic Wire.	X	
Metal Coil Coating	EPA–450/2–77–008—Control of Volatile Organic Emissions from Existing Stationary Sources, Volume II: Surface Coating of Cans, Coils, Paper, Fabrics, Automobiles, and Light-Duty Trucks.	X	
Natural Gas/Gasoline Processing	EPA–450/2–83–007—Control of Volatile Organic Compound Equipment Leaks from Natural Gas/Gasoline Processing Plants.	X	
Paper and Fabric Coating	EPA–450/2–77–008—Control of Volatile Organic Emissions from Existing Stationary Sources, Volume II: Surface Coating of Cans, Coils, Paper, Fabrics, Automobiles, and Light-Duty Trucks.	X	
Resin Manufacturing (High-Density Polyethylene, Polypropylene, and Polystyrene).	EPA–450/3–83–008—Control of Volatile Organic Compound Emissions from Manufacture of High-Density Polyethylene, Polypropylene, and Polystyrene Resins.	X	
Refineries	EPA–450/2–77–025—Control of Refinery Vacuum Producing Systems, Wastewater Separators and Process Unit Turnarounds.	X	
	EPA–450/2–78–036—Control of Volatile Organic Compound Leaks from Petroleum Refinery Equipment.	X	
Rubber Tire Manufacturing	EPA–450/2–78–030—Control of Volatile Organic Emissions from Manufacture of Pneumatic Rubber Tires.	X	
Ship Coating	61 FR 44050—Control Techniques Guidelines for Shipbuilding and Ship Repair Operations (Surface Coating).	X	
Wood Coating (Flat Wood Paneling)	EPA–450/2–78–032—Control of Volatile Organic Emissions from Existing Stationary Sources, Volume VII: Factory Surface Coating of Flat Wood Paneling.	X	
Flat Wood Paneling Coatings	EPA–453/R06–004—Control Techniques Guidelines for Flat Wood Paneling Coatings.		X
Paper, Film and Foil	EPA–453/R–07–004—Control Techniques Guidelines for Paper, Film, and Foil Coatings.		X

* * * * *

■ 4. Section 52.237 is amended by adding paragraph (b) to read as follows:

§ 52.237 Part D disapproval.

* * * * *

(b) The following Reasonably Available Control Technology (RACT) determinations are disapproved because they do not meet the requirements of Part D of the Clean Air Act.

(1) Sacramento Air Quality Management District.

(i) RACT Determinations for the Pharmaceutical Products Manufacturing Source Category and the Kiefer Landfill (volatile organic compounds only), in the submittal titled ''Reasonably Available Control Technology (RACT) as Applicable to the 8-Hour Ozone Standard,'' dated October 26, 2006, as adopted on October 26, 2006 and submitted on July 11, 2007.

(ii) [Reserved]

(2) [Reserved]

[FR Doc. 2016–18900 Filed 8–11–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2012–0985; FRL–9950–50–Region 6]

Approval and Promulgation of Air Quality Implementation Plans; Texas; Interstate Transport of Air Pollution for the 2008 Ozone National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is disapproving the portion of a Texas State Implementation Plan (SIP) submittal pertaining to interstate transport of air pollution which will significantly contribute to nonattainment or interfere with maintenance of the 2008 ozone National Ambient Air Quality Standard (NAAQS) in other states. Disapproval establishes a 2-year deadline for the EPA to promulgate a Federal Implementation Plan (FIP) for Texas to address the Clean Air Act (CAA) interstate transport requirements pertaining to significant contribution to nonattainment and interference with maintenance of the 2008 ozone NAAQS in other states, unless the EPA approves a SIP that meets these requirements. Disapproval does not start a mandatory sanctions clock for Texas.

DATES: This rule is effective on September 12, 2016.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R06–OAR–2012–0985. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy. Publicly available docket materials are available either electronically through *http://www.regulations.gov* or in hard copy at EPA Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733.

FOR FURTHER INFORMATION CONTACT: Carl Young, 214–665–6645, *young.carl@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us,'' and ''our'' means the EPA.

I. Background

This rulemaking addresses an infrastructure SIP submittal from the state of Texas addressing, among other things, the requirements of CAA section 110(a)(2)(D)(i)(I), also known as the good neighbor provision (or interstate transport prongs 1 and 2), with respect to the 2008 ozone NAAQS. The background for this action is discussed in detail in our April 11, 2016 proposal (81 FR 21290). In that action we proposed to disapprove the portion of the December 13, 2012 Texas SIP submittal pertaining to CAA section 110(a)(2)(D)(i)(I) which requires that the State prohibit any emissions activity within the state from emitting air pollutants which will significantly contribute to nonattainment (prong 1) or interfere with maintenance (prong 2) of the 2008 ozone NAAQS in other states.[1] In proposing to disapprove the SIP submittal as to prongs 1 and 2 of the good neighbor provision, we noted several deficiencies in Texas' submittal: (1) Texas limited its discussion of data only to areas designated nonattainment in states that are geographically closest to Texas (Arizona, Arkansas, Colorado, Illinois, Indiana, Louisiana, Mississippi, Missouri, Tennessee, and Wisconsin); and (2) Texas did not give the ''interfere with maintenance'' clause of CAA section 110(a)(2)(D)(i)(I) independent significance because its analysis did not attempt to evaluate the potential impact of Texas emissions on areas that are currently measuring clean data, but that may have issues maintaining that air quality.[2] Finally, the EPA explained that Texas and other states could no longer rely on the implementation of the Clean Air Interstate Rule (CAIR) to satisfy emission reduction obligations with respect to the 2008 ozone NAAQS (81 FR 21290, 21294–5). The EPA is finalizing its proposed disapproval in this action.

We received three comments during the comment period on our proposed SIP disapproval. The comments were submitted by the State of Texas (Texas Commission on Environmental Quality ''TCEQ''), Luminant (a Texas electricity producer) and a member of the public. A synopsis of the comments and our responses are provided below.

II. Response to Comments

Comment: Comments were received from a member of the public that was supportive of the EPA's basis for its proposed action, but added that (1) the public can better understand how we are using the most current information if we clarify and explain how the projections and modeling discussed in the evaluation for our proposal are informed by recent ozone monitoring data, and (2) the commenter stated that the EPA took too long to propose action on the Texas SIP revision, noting that Texas would benefit from earlier review of its analysis by the EPA.

Response: We agree with the commenter's conclusion that Texas's SIP submittal was inadequate to address the statutory interstate transport requirements with respect to the 2008 ozone NAAQS. With respect to the commenter's first concern, the projections and modeling released c in the August 4, 2015 NODA and the proposed CSAPR Update, which we also o recited in the EPA's proposed action on the Texas SIP submittal. In our CSAPR Update proposal, we explained how the CSAPR Update Rule proposed to use recent ozone monitoring data to inform our evaluation of interstate transport (80 FR 75706, 75724). We proposed to identify as nonattainment receptors those monitoring sites that (1) measured ozone concentrations that exceed the NAAQS based on monitoring data from years 2012–2014, and (2) are projected to exceed the NAAQS in 2017 based on an average design value.[3] We proposed to identify maintenance receptors as those monitoring sites that have measured ozone concentrations that meet the NAAQS (clean data) based on monitoring data from years 2012–2014 and are projected to exceed the NAAQS in 2017 based on a maximum or average design value. We proposed this method of projecting from recent monitoring data to 2017 to identify maintenance receptors, since the monitoring sites of the proposed maintenance receptors currently meeting the NAAQS could be subject to conditions that may allow violations to reoccur and therefore may have future maintenance concerns. For more information about how the EPA identified 2017 nonattainment and maintenance receptors, please see pages 75723–75726 in the proposed CSAPR Update. (80 FR 75706). Today's rulemaking does not address which monitoring sites are identified as nonattainment and maintenance receptors with respect to interstate transport for the 2008 ozone NAAQS. Such determination, including more recent ozone monitoring data which will inform that analysis, will be addressed in the EPA's final CSAPR Update and are outside the scope of this final action. The EPA's disapproval is based on the inadequacies in the analysis provided in Texas's SIP submittal, as described in this document and in EPA's proposed action on that SIP.

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[1] In a separate action, we disapproved the portion of the SIP submittal pertaining to the CAA section 110(a)(2)(D)(i)(II) requirement to address the interstate transport of air pollution which will interfere with other states' programs for visibility protection (81 FR 296, January 5, 2016). We proposed to approve the other portions of the infrastructure SIP submittal on February 8, 2016 (81 FR 6483).

[2] In addition, the EPA cited at proposal certain technical information the agency had released in order to facilitate efforts to address interstate transport requirements for the 2008 ozone NAAQS, and that this information was used to support the proposed Cross-State Air Pollution Rule Update for the 2008 ozone NAAQS (CSAPR Update) (81 FR 21299, 21292). We noted that such information contradicts Texas' conclusions that its SIP contained adequate provisions to meet the CAA interstate transport requirements with respect to the 2008 ozone NAAQS. See Notice of Data Availability (NODA), 80 FR 46271, (August 4, 2015) and the proposed CSAPR Update, 80 FR 75706 (December 3, 2015). We also noted at proposal that the EPA technical information in the NODA and the proposed CSAPR Update accounted for the emission reductions resulting from controls listed in the SIP, implemented within the state, and nonetheless showed that Texas will contribute to downwind air quality problems. The CSAPR Update, however, is outside the scope of this action, and is irrelevant to the question of whether the Texas SIP should be disapproved.

With respect to the timeliness of the EPA's action on the Texas SIP submittal, CAA section 110(k)(2) requires the EPA to act on SIPs within one year after a submittal is determined to be complete. We determined that the Texas infrastructure SIP submittal, which includes transport, was complete on December 20, 2012. While the EPA generally agrees that prompt action on state SIP submittals can be beneficial to the states' planning efforts, in this case, the D.C. Circuit's decision in *North Carolina* v. *EPA,* 531 F.3d 896, 908–911 (D.C. Cir. 2008) provided the holding that states must give the "interfere with maintenance" clause of CAA section 110(a)(2)(D)(i)(I) independent significance, which Texas failed to do.

Comment: The TCEQ stated that it does not support the EPA's proposed disapproval of the state's interstate transport portion of its SIP submittal because the TCEQ's interstate transport analysis adequately addresses the requirements of CAA section 110(a)(2)(D)(i)(I). Specifically, TCEQ stated that the EPA failed to issue guidance in a timely manner for states to use in developing infrastructure and transport SIP revisions for the 2008 ozone NAAQS. TCEQ therefore contends that it is inappropriate for the EPA to conclude that the state's analysis of ozone contributions to other areas is incomplete when the EPA did not provide timely guidance stating what would constitute a complete analysis. TCEQ explained that its SIP revision was submitted on December 13, 2012 in order to meet the January 4, 2013 deadline by which the EPA was court-ordered to issue findings of failure to submit infrastructure SIPs for the 2008 ozone NAAQS. TCEQ notes that the EPA did not issue infrastructure SIP guidance until September 13, 2013, eight months following the January 2013 deadline, which did not contain any information on what would constitute an adequate interstate transport analysis. TCEQ further notes that the EPA did not provide information to states regarding interstate transport for the 2008 ozone NAAQS until 2015, through information provided in a January 22, 2015 memo, an August 4, 2015 NODA, and the December 3, 2015 CSAPR Update proposal, which was well after the state's SIP submittal. Therefore, as a result of the EPA's lack of timely transport guidance for the 2008 ozone standard and subsequent NODA regarding 2017 nonattainment and maintenance receptor linkages and contributions, TCEQ contends that it was forced to expend effort and resources to develop its SIP revision without knowing how the EPA would evaluate Texas' interstate transport obligation. Further, the EPA has routinely failed to issue timely guidance for SIP revisions and to even meet statutory SIP review deadlines in the CAA. As a result, the EPA has disrupted the SIP development process nationwide, undermining the states' ability to submit sufficient SIP revisions.

Response: We disagree that Texas' December 13, 2012 SIP submittal containing the state's transport analysis adequately addressed the requirements of CAA section 110(a)(2)(D)(i)(I). Rather, the state's analysis was deficient to address the statutory requirements, as detailed in the proposal and in more detail in this document. CAA section 110(a)(2)(D)(i)(I) requires that for a new or revised standard, each SIP must contain adequate provisions to prohibit any emissions activity within the state from emitting air pollutants that will "contribute significantly to nonattainment" or "interfere with maintenance" of the applicable air quality standard in any other state—here being the 2008 ozone standard. (81 FR 21290–1, April 11, 2016). Texas submitted an analysis of monitoring data, wind patterns, emissions data and emissions controls and concluded that based on monitoring data, due to decreases in ozone design values and existing control measures, emissions from sources from within the state do not contribute significantly to nonattainment or interfere with maintenance of the 2008 ozone NAAQS in other states. We find that Texas' analysis was not adequate because Texas limited its discussion of data only to areas designated nonattainment in states that are geographically closest to the state and we find this approach incomplete, (as detailed in our proposal), since the state did not consider other areas that were not formally designated as nonattainment. (81 FR 21292). Moreover, the state did not give the "interfere with maintenance" clause of CAA section 110(a)(2)(D)(i)(I) independent significance, consistent with the D.C. Circuit's decision in *North Carolina* v. *EPA,* 531 F.3d 896, 908–911 (D.C. Cir. 2008), because its analysis did not attempt to evaluate the potential impact of Texas emissions on areas that are currently measuring clean data, but that may have issues maintaining that air quality. (81 FR 21292). As we noted at proposal the EPA's most recent technical information demonstrates that emissions from Texas do impact air quality in other states relative to the 2008 ozone NAAQS. (81 FR 21292–3). With regard to the timelines of EPA guidance, in *EPA* v. *EME Homer City Generation, L.P.,* the Supreme Court clearly held that "nothing in the statute places the EPA under an obligation to provide specific metrics to States before they undertake to fulfill their good neighbor obligations." 134 S. Ct. 1584, 1601 (2014).[4] While we have taken a different approach in some prior rulemakings by providing states with an opportunity to submit a SIP after we quantified the states' budgets (*e.g.,* the

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[3] The design value for the 2008 ozone NAAQS is the 3-year average of the annual 4th highest daily maximum 8-hour ozone concentration at a monitoring site.

[4] "Nothing in the Act differentiates the Good Neighbor Provision from the several other matters a State must address in its SIP. Rather, the statute speaks without reservation: Once a NAAQS has been issued, a State 'shall' propose a SIP within three years, § 7410(a)(1), and that SIP 'shall' include, among other components, provisions adequate to satisfy the Good Neighbor Provision, § 7410(a)(2)." *EPA* v. *EME Homer City Generation, L.P.,* 134 S. Ct. at 1600.

NO_XSIP Call and CAIR[5]), the CAA does not require such an approach. Regarding the commenter's contention that the EPA's alleged inability to review SIP submittals within the CAA timelines undermines the ability of states to submit sufficient SIPs, the State's ability to submit a sufficient SIP that meets the applicable requirements is unrelated to the EPA's timeline for review.

Comment: TCEQ and Luminant both state that the EPA's public notice on the proposed disapproval is not meaningful because they contend that the outcome was predetermined when the EPA proposed a FIP for Texas in the proposed CSAPR Update. They stated that at the time of the proposed FIP to update CSAPR, the EPA had taken no action on the previously submitted SIP submittal from Texas addressing interstate transport with respect to the 2008 ozone NAAQS. The commenters contend that the EPA should have evaluated the SIP submittal prior to proposing a CSAPR Update that included Texas. The commenters also stated that we had not satisfied the prerequisites of CAA section 110(c)(1) when we issued the proposed FIP for Texas in the proposed CSAPR Update. The commenters therefore contend that the proposed SIP disapproval is only a post hoc rationalization for the proposed CSAPR Update, and our approach is unlawful and impermissibly treads on cooperative federalism required under the CAA. Lastly, the commenters claim that had we reviewed the SIP revision before proposing the CSAPR Update for Texas, the state would have had the opportunity contemplated by the CAA to correct any problems with its SIP in a timely fashion and avoid the imposition of the FIP.

Response: We disagree with the commenters that the proposed disapproval was predetermined when the EPA issued the proposed CSAPR Update that included a FIP for Texas. Our proposal to disapprove the Texas SIP provided proper notice and an opportunity for public comment, as legally required, and provided distinct bases for the proposed disapproval. Importantly, the proposed disapproval of the Texas SIP allowed an opportunity for submittal of any information that could have changed our proposed views concerning (1) the adequacy of the SIP submittal, and (2) the effect of Texas emissions on ozone levels in downwind states as demonstrated in the modeling and contribution information the EPA relied upon for its proposed disapproval. The EPA has not received any information demonstrating the identified inadequacies of the SIP submittal and the data showing the effect of Texas emissions in downwind states are inaccurate.

Whether the EPA appropriately proposed the CSAPR Update is outside the scope of this action, and is irrelevant to the question of whether the Texas SIP should be disapproved. The bases for the disapproval are further explained in both the proposal and this final action, and do not rely upon the proposed CSAPR Update. As described in the proposal and earlier in this document, whether or not the EPA had proposed the CSAPR Update, Texas' SIP submittal failed to include an analysis that appropriately evaluated the impact of state emissions on areas in other states, regardless of current nonattainment designations and considering the ability of areas currently measuring clean data to maintain that standard. These deficiencies are completely independent of any analysis conducted to support the CSAPR Update proposal.

Moreover, while the CSAPR Update proposal also relied upon the same modeling and contribution information to identify which states might be subject to a FIP in the final rulemaking, in the absence of an approvable SIP, the proposed disapproval of the Texas SIP did not rely upon the proposed findings in the CSAPR Update but rather cited, in addition to other deficiencies identified with the Texas SIP, technical data that was relevant to and informative for both proposals.

Our actions are consistent with CAA section 110(c) prerequisites in promulgating a FIP. In our December 3, 2015 **Federal Register** notice, we proposed to include Texas in the CSAPR Update (80 FR 75706). In that proposal we recognized that we could not promulgate a FIP for any state, including Texas, in the final CSAPR Update unless we found that the state had failed to make an approvable SIP submittal (80 FR 75719–20). A proposed rulemaking does not constitute a promulgation of a rule by the EPA, and therefore the proposed CSAPR Update does not constitute a "predetermined outcome" of EPA's review of Texas' SIP submittal, as the commenters describe, nor a promulgated FIP under CAA section 110(c). Were the EPA to finalize an approval of Texas' SIP, the EPA would not finalize the proposed inclusion of Texas in any final CSAPR Update. However, for the reasons described earlier, the EPA is finalizing its disapproval of Texas' SIP. However, this final action does not promulgate a FIP nor make any final determination regarding whether and when the EPA will promulgate a FIP. The EPA will determine whether to issue a FIP in the context of the CSAPR Update in the rulemaking for that action, and thus any concerns regarding the EPA's authority to issue a FIP are appropriately raised only in the context of that rulemaking.

Finally, the EPA disagrees with the commenters' claim that had we reviewed the SIP revision before proposing the CSAPR Update for Texas, the state would have had the opportunity contemplated by the CAA to correct any problems with its SIP in a timely fashion in order to avoid the imposition of the FIP. Contrary to commenters' assertions, CAA does not contemplate that a state have an opportunity to correct deficiencies with its SIP either before the EPA takes action to act on the SIP or before the EPA imposes a FIP after disapproval of a SIP. CAA section 110(c) provides that the EPA "shall promulgate a [FIP] *at any time* within two years after" the EPA either finds that a state has failed to make a required submittal or disapproves a SIP, in whole or in part. As the Supreme Court confirmed in *EPA* v. *EME Homer City Generation. L.P.*, "EPA is not obliged to wait two years or postpone its action even a single day: The Act empowers the Agency to promulgate a FIP 'at any time' within the two-year limit." *EPA* v. *EME Homer City Generation, L.P.*, 134 S. Ct. 1584, 1600–01 (2014). The EPA notes, however, that states have the ability at any time, including before or after the imposition of a FIP, to submit an approvable SIP, which corrects any deficiency.

Comment: TCEQ commented that we inappropriately stated that it should have considered possible contributions to downwind areas that are not designated nonattainment but may nonetheless measure exceedances of the NAAQS. TCEQ further stated that we fail to mention how Texas might have accomplished this theoretical exercise particularly without EPA guidance on how to develop its transport SIP and considering the EPA relies on nationwide modeling to determine potential exceedances in areas that are attaining the NAAQS that is not made available to states prior to the statutory due dates for state transport SIPs. The TCEQ concedes that the EPA may now consider the CSAPR schema to be appropriate guidance for transport regulation, but contends that it is still not possible for states to effectively respond with timely transport SIPs. The commenter again notes that the EPA did not explain what type of transport analysis would be considered satisfactory when the EPA issued SIP guidance in 2013.

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[5] For information on the NO_X SIP call see 63 FR 57356 (October 27, 1998). For information on CAIR (the Clean Air Interstate Rule) see 70 FR 25162 (May 12, 2005).

Response: Regardless of an air quality designation, any area may violate the NAAQS if upwind emissions affecting air quality are not adequately controlled. The EPA has routinely interpreted the obligation to prohibit emissions that "significantly contribute to nonattainment" of the NAAQS in downwind states to be independent of formal designations because exceedances can happen in any area.[6] Nothing in the CAA limits States' obligations under the good neighbor provision to downwind areas that have been formally designated nonattainment. To the contrary, CAA section 110(a)(2)(D)(i)(I) requires States to prohibit emissions that "*will* contribute significantly to nonattainment in . . . any other State." (emphasis added). The future tense demonstrates that Congress intended this requirement to be forward-looking and apply to areas that will be in nonattainment regardless of formal designation. An area with air quality that is projected to exceed the NAAQS would be in nonattainment, and thus not meeting public health-based standards, regardless of whether it has been formally designated as a nonattainment area. An upwind state cannot be relieved of its obligation to address interstate transport of air pollution merely because of a lack of formal designation. Thus, Texas should have considered possible contributions to downwind areas that are not designated nonattainment but may nonetheless measure exceedances of the NAAQS in considering whether Texas emissions significantly contribute to nonattainment in another state.

With respect to the "interfere with maintenance" requirement, the court in *North Carolina* v. *EPA,* (531 F.3d 896, D.C. Cir. 2008), was specifically concerned with areas not designated nonattainment when it rejected the view that "a state can never 'interfere with maintenance' unless the EPA determines that at one point it 'contribute[d] significantly to nonattainment.'" 531 F.3d at 910. The court pointed out that areas barely attaining the standard due in part to emissions from upwind sources would have "no recourse" pursuant to such an interpretation. *Id.* Accordingly, and as described in the proposal, the court explained that the regulatory authority must give "independent significance" to the maintenance prong of CAA section 110(a)(2)(D)(i)(I) by separately identifying such downwind areas for purposes of defining states' obligations pursuant to the good neighbor provision. Thus, Texas should have considered the potential impact of its emissions on areas that are currently measuring clean data, but may have issues maintaining that air quality.

Although the TCEQ questions how it could have completed such an analysis without explicit guidance from the EPA and before the EPA had conducted air quality modeling evaluating downwind air quality and contributions, as explained earlier, states bear the primary responsibility for demonstrating that their plans contain adequate provisions to address the statutory interstate transport provisions and the EPA is not required to issue guidance. In separate interstate transport actions, the EPA has reviewed and finalized action on interstate transport SIPs in states where air quality modeling was not available or where the total weight of evidence for finalizing action on the state's SIP was not solely based on air quality modeling, according to these standards.[7] As evidenced by these actions, consideration of monitoring data is one valid way to evaluate potential interstate transport impacts, but it does not absolve a state from evaluating its downwind impact regardless of formal area designations and considering the requirements of both prongs of the good neighbor provision. As we noted above and as found by the Supreme Court in *EME Homer City Generation, L.P.,* the lack of guidance does not relieve either the states of the obligation to submit SIPs that address CAA section 110(a)(2)(D)(i)(I) nor the EPA of the obligation to review such SIPs consistent with the statutory requirements of the good neighbor provision. For the 2015 ozone NAAQS, we plan to provide information pertaining to interstate transport of air pollution later this year.[8] Interstate transport SIPs for the 2015 ozone NAAQS are due October 26, 2018. We plan to continue our ongoing dialogue with states to assist in developing an appropriate transport SIP.

Comment: TCEQ and Luminant both state that in our CSAPR Update proposal the EPA did not give independent effect to both the "contribute significantly to nonattainment" and the "interfere with maintenance" requirements as nonattainment and maintenance receptors are treated exactly the same way as far as linkages to states are defined and emission budgets are set. Luminant also claims that the EPA would be in violation of the Supreme Court in *EME Homer City Generation, L.P.* if we impose the same "cost-effective controls" to address both interference with maintenance and significant contribution to nonattainment.

Further, the comments state that because some states are linked to receptors in marginal nonattainment areas, the EPA is requiring emissions reductions from upwind states, including Texas, to assist states that do not have make emission reductions or institute control strategies of their own. Further, the comments claim that we have failed to identify any balance between local controls in areas with potential maintenance problems and reductions that it is requiring of states upwind that it models as contributing at least 1% of the relevant NAAQS to these areas with modeled, not monitored, issues.

The commenters also disagree with the EPA's finding that the Texas SIP submittal did not give independent significance to the CAA "interfere with maintenance'' requirement and contend that we have misconstrued that requirement by stating that TCEQ did not evaluate areas currently measuring clean data. Luminant contends that Texas' SIP does give independent significance to the ''interfere with maintenance'' clause. TCEQ claims that the EPA has not promulgated a rule that identifies a required or recommended methodology for the EPA or states to give independent consideration to possible contributions that may interfere with maintenance in downwind areas, and contend that it is arbitrary and capricious for the EPA to propose disapproval for failure to meet a standard or requirement that did not exist at the time the statutory obligation matured.

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[6] See, *e.g.,* Clean Air Interstate Rule, 70 FR 25162, 25265 (May 12, 2005) ("As to impacts, CAA section 110(a)(2)(D) refers only to prevention of 'nonattainment' in other States, not to prevention of nonattainment in designated nonattainment areas or any similar formulation requiring that designations for downwind nonattainment areas must first have occurred."); Cross-State Air Pollution Rule, 76 FR 48208, 48211 (Aug. 8, 2011) (evaluating nonattainment and maintenance concerns based on modeled projections); Brief for Respondents U.S. Environmental Protection Agency at 23–24, *EME Homer City Generation, L.P.* v. *EPA,* Case No. 11-1302 (D.C. Cir. Jan. 16, 2015), ECF No. 1532516 (defending the EPA's identification of air quality problems in CSAPR independent of area designations). *Cf.* Final Response to Petition from New Jersey Regarding SO_2 Emissions From the Portland Generating Station, 76 FR 69052 (Nov. 7, 2011) (finding facility in violation of the prohibitions of CAA section 110(a)(2)(D)(i)(I) with respect to the 2010 SO_2 NAAQS prior to issuance of designations for that standard).

[7] See, *e.g.,* Air Quality State Implementation Plans; Approvals and Promulgations: Utah; Interstate Transport of Pollution for the 2006 $PM_{2.5}$ NAAQS May 20, 2013 (78 FR 29314); Final Rule, 78 FR 48615 (August 9, 2013); Approval and Promulgation of Implementation Plans; State of California; Interstate Transport of Pollution; Significant Contribution to Nonattainment and Interference With Maintenance Requirements, Proposed Rule, 76 FR 146516, 14616–14626 (March 17, 2011); Final Rule, 76 FR 34872 (June 15, 2011); Approval and Promulgation of State Implementation Plans; State of Colorado; Interstate Transport of Pollution for the 2006 24-Hour $PM_{2.5}$ NAAQS, Proposed Rule, 80 FR 27121, 27124–27125 (May 12, 2015); Final Rule, 80 FR 47862 (August 10, 2015).

[8] See pages 6–7 of the attachment to the October 1, 2015 EPA memorandum "Implementing the 2015 Ozone National Ambient Air Quality Standards" from Janet McCabe, Acting Assistant Administrator, Office of Air and Radiation to Regional Administrators, Regions 1–10, *https://www.epa.gov/sites/production/files/2015-10/documents/implementation_memo.pdf.*

Response: As described in the proposal, the EPA proposed disapproval in part because the Texas SIP submittal did not address the potential impact of Texas emissions on maintenance areas. Reiterating our position explained in the proposal, the D.C. Circuit in *North Carolina* explained that the regulatory authority must give ''independent significance'' to the maintenance prong of CAA section 110(a)(2)(D)(i)(I) by evaluating the impact of upwind state emissions on downwind areas that, while currently in attainment, are at risk of future nonattainment, considering historic variability. *North Carolina* v. *EPA,* 531 F.3d 896, 908–911 (D.C. Cir. 2008). While one commenter contends that Texas evaluated the interference with maintenance prong and concluded monitoring data do not suggest that emissions from Texas contribute significantly to nonattainment or interfere with maintenance of the 2008 ozone NAAQS for areas in any other state, nothing in Texas' SIP submittal indicates that it performed any analysis to support its conclusion as the State limited its discussion of data only to certain areas designated nonattainment and did not consider whether those or any other areas might have trouble maintaining the standard even if they measured clean data. Thus, contrary to the commenter's assertion, Texas did not give independent meaning to the interference with maintenance prong by evaluating the impact of upwind state emissions on downwind areas that, while currently in attainment, are at risk of future nonattainment, as required by the statute and as clarified by the D.C. Circuit in *North Carolina.*

The EPA disagrees with the commenter's assertion that this standard or requirement did not exist at the time the statutory obligation to submit a transport SIP matured. At the time Texas was obligated to submit a SIP addressing interstate transport requirements for the 2008 ozone NAAQS, CAA section 110(a)(2)(D)(i)(I) clearly required states to submit a plan containing adequate provisions prohibiting any source or other type of emissions activity within the state from emitting any air pollutant in amounts which will interfere with maintenance by any other state with respect to a particular NAAQS. This requirement has not changed since Texas' obligation to submit a transport SIP matured, and contrary to commenter's assertion, the EPA is not obligated to identify a required or recommended methodology for giving independent consideration to possible contributions that may interfere with maintenance in downwind areas prior to proposing action on a SIP addressing such statutory requirement. Nonetheless, the State's SIP made no attempt to evaluate the maintenance prong with respect to the 2008 ozone NAAQS aside from its conclusory assertion that the requirements were satisfied.

To the extent the commenter has raised concerns with respect to the EPA's interpretation and application of the CAA, including the ''interfere with maintenance'' clause, in the context of the CSAPR Update rulemaking, such comments are appropriately raised and addressed in that rulemaking. The EPA is not finalizing in this rule any determinations regarding the identification of specific downwind maintenance receptors, the magnitude of Texas' contribution to those receptors, and the quantity of any emission reductions that might be necessary. Such determinations will be made in the context of the CSAPR Update rulemaking. To the extent that Luminant refers to the EPA's approach as not compliant with the Supreme Court's *EME Homer City Generation, L.P.* decision, this comment relates to the CSPAR Update rulemaking and not our action today. Thus, it is outside the scope of this action and would be more appropriately addressed in that separate rulemaking.

Comment: TCEQ claims that the EPA has not demonstrated that a contribution by upwind states of 1% of the NAAQS will interfere with maintenance in identified maintenance areas. Further the TCEQ contends that the EPA has not demonstrated that a 1% of the NAAQS contribution to modeled emissions in maintenance areas is appropriate for linking an upwind state to a maintenance monitor. Further, they contend that EPA has not demonstrated that the amount of reductions necessary to cure a contribution to nonattainment is also appropriate to ensure that an upwind state is not interfering with maintenance. Lastly, TCEQ states that the 1% contribution threshold is arbitrary.

Response: The EPA explained in the CSPAR Update proposal its reasoning for why we believe it appropriate to use the same approach used in CSAPR to establish a 1% air screening threshold for the evaluation of interstate transport requirements for the 2008 ozone NAAQS, including the interference with maintenance requirement. 81 FR 21292–94. The commenter does not explain its allegations that the 1% threshold is arbitrary nor does the commenter explain how the EPA has not demonstrated this threshold is appropriate to show interference by upwind states with maintenance in identified maintenance areas.

Nonetheless, while the EPA cited the modeling conducted for the CSAPR Update as showing Texas may significantly contribute to nonattainment or interfere with maintenance of the 2008 ozone NAAQS in downwind states, we did not propose to make a specific finding of contribution or to quantify any specific emissions reduction obligation. We did not rely upon a 1% contribution threshold for this action. Rather, the evaluation of whether emissions from Texas significantly contribute to nonattainment or interfere with maintenance of the 2008 ozone NAAQS downwind, relying upon the use of a 1% contribution threshold, and if so what reductions are necessary to address that contribution, is being conducted in the context of the CSAPR Update rulemaking. Accordingly, this comment relates to the CSPAR Update rulemaking and not our action today. Thus, it is outside the scope of this action and would be more appropriately addressed in that separate rulemaking. The EPA will consider timely-submitted comments regarding the EPA's air quality modeling and various associated legal and policy decisions in finalizing that rulemaking.

Comment: TCEQ stated that it supports the use of ambient air quality monitoring data as the only valid basis for making nonattainment designations and identifying nonattainment and maintenance receptors and that it does not support the use of modeling as the basis for designations or identifying either nonattainment or maintenance receptors for transport. TCEQ contends that using modeling for these actions could result in major capital expenditures for industry to fix something that may not be a real problem, and claims that to base these actions on modeling is inconsistent with historical and present EPA policies. TCEQ also notes that the EPA does not redesignate an area to attainment when an area models attainment as part of an attainment demonstration, but rather uses monitoring data to verify attainment before redesignation.

Response: While the EPA does rely on ambient air quality monitoring data to make decisions on ozone nonattainment designations and redesignations, the EPA has routinely based its determination of receptors for purposes of evaluating interstate ozone transport on air quality modeling projections.[9] This is because, regardless of designation, any area may violate the NAAQS if upwind emissions affecting air quality are not adequately controlled, and areas currently measuring clean data may still violate the NAAQS if conditions change such that attainment with the NAAQS can no longer be maintained. Thus, the means by which the EPA makes decisions with respect to area designations is not relevant to our identification of receptors that should be evaluated for interstate transport of air pollution. In *North Carolina* v. *EPA,* the D.C. Circuit concluded that the EPA's reliance on future projections to identify such receptors was a reasonable application of the statute. *North Carolina,* 531 F.3d at 914. Nonetheless, while the EPA has relied upon modeling to identify downwind air quality problems, the EPA has also stated that states may consider other types of data when evaluating interstate transport in developing their SIPs. See Memorandum from William T. Harnett to Regional Air Division Directors, Regions I–X, ''Guidance on SIP Elements Required Under [CAA] Sections 110(a)(1) and (2) for the 2006 24-Hour Fine Particle ($PM_{2.5}$) National Ambient Air Quality Standards (NAAQS)'', September 25, 2009.[10] Indeed, as described earlier, the EPA has regularly evaluated interstate transport SIPs in western states, where modeling has not typically been available, considering monitored data in a manner that is consistent with the standards described in this document.

Comment: TCEQ stated that we failed to give comments on the adequacy of the State's interstate transport analysis during the State public comment period and that the lack of comments led the State to believe that the submitted analysis was adequate to show how Texas contributes to other states' ozone concentrations.

Response: The EPA's authority and obligation under the Act is to review a SIP submittal and determine whether it meets the applicable requirements of the Act and regulations, regardless of whether we commented on a State's proposed SIP during its State rulemaking process. There is no requirement in the Act that the EPA must review, evaluate, and comment on a State's proposed SIP revision during the state rulemaking process, and no reasonable or legal basis for states to assume that the EPA's choosing to not provide comment on their analysis during the state public comment period constitutes the Agency's endorsement of such analysis.

Comment: Luminant stated that the EPA needs to revise the CSAPR ozone season NO_X budgets in accordance with the D.C. Circuit's remand in *EME Homer City Generation, L.P.* before the EPA can evaluate Texas' SIP submittal. See *EME Homer City Generation, L.P. v EPA,* 795 F.3d 118 (D.C. Cir. 2015). Luminant stated that, by failing to issue new budgets for the 1997 ozone NAAQS, we are in violation of the D.C. Circuit's specific remand instructions. The commenter contends that the EPA cannot rationally evaluate Texas' SIP submittal until we comply with the court's remand. The commenter specifically contends that the EPA must replace the CSAPR budgets with lawful budgets that do not require more control than necessary to comply with the 1997 ozone NAAQS, and that otherwise, the EPA has no basis to disapprove the Texas SIP submittal. By failing to establish lawful budgets, the commenter claims that the EPA does not have the information necessary to evaluate additional reductions associated with Texas' plan to comply with the 2008 ozone NAAQS.

Response: The EPA has an independent statutory obligation to evaluate Texas' SIP submittal addressing the good neighbor provision with respect to the 2008 ozone NAAQS. The fact that the EPA has not yet completed its response to the D.C. Circuit's remand to address interstate transport with respect to the 1997 ozone NAAQS does not preclude either the state from addressing its own statutory obligation with respect to the 2008 ozone NAAQS pursuant to CAA section 110(a)(2)(D)(i)(I) or the EPA from fulfilling its statutory obligation to review the SIP submittal pursuant to CAA section 110(k). As noted earlier, the EPA has identified several deficiencies with the interstate transport analysis in the Texas SIP submittal that are unrelated to the CSAPR rulemakings either with respect to the 1997 or 2008 ozone standards.

The EPA has proposed its intended response to address the D.C. Circuit's remand of the CSAPR ozone season NO_X budgets in the context of the CSAPR Update, which is expected to be finalized later this year. The commenter does not explain how the EPA's finalization of this action with respect to the 1997 ozone standard would aid in the state's evaluation of transport with respect to the 2008 ozone standard. Nonetheless, should the commenter have any concerns about the EPA's approach to addressing the court's remand, the appropriate venue for the EPA's evaluation of those concerns is in the context of the CSAPR Update rulemaking. Any concerns are outside the scope of this rulemaking.

Comment: Luminant stated that we must reopen the comment period for the CSAPR Update rulemaking. Luminant contends that comments previously submitted on the CSAPR Update proposal have limited utility because the EPA's rationale for disapproving Texas' SIP submittal was not known at the time those comments were submitted for that proposal.

Response: As noted earlier, the EPA has identified several deficiencies with the interstate transport analysis in the Texas SIP submittal that are unrelated to the CSAPR Update rulemaking. Moreover, any request to reopen the public comment period on the CSAPR Update is not appropriately raised in this rulemaking.

III. Final Action

For the reasons described in the proposal and in this final action, the EPA is disapproving a portion of the December 13, 2012 SIP submittal from Texas seeking to address the required infrastructure element under CAA section 110(a)(2)(D)(i)(I) with respect to the State's significant contribution to nonattainment or interference with maintenance of the 2008 ozone NAAQS in other states, known as prongs 1 and 2 of the good neighbor provision.

In a separate action, we disapproved the portion of the SIP submittal pertaining to the CAA section 110(a)(2)(D)(i)(II) requirement to address the interstate transport of air pollution which will interfere with other states' programs for visibility protection (81 FR 296, January 5, 2016). We proposed to approve the other portions of the infrastructure SIP submittal on February 8, 2016 (81 FR 6483). We expect to take final action on the other portions of the Texas infrastructure SIP at a later date.

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[9] See CSAPR (76 FR 48208, August 8, 2011), CAIR (70 FR 25162, May 12, 2005) and the NO_X SIP call (63 FR 57356, October 27, 1998).

[10] *https://www3.epa.gov/ttn/naaqs/aqmguide/collection/cp2/20090925_harnett_section_110(a)_sip_2006_24-hr_pm2.5_naaqs.pdf.*

Pursuant to CAA section 110(c)(1), this disapproval establishes a 2-year deadline for the EPA to promulgate a FIP for Texas to address the requirements of CAA section 110(a)(2)(D)(i) with respect to the 2008 ozone NAAQS unless Texas submits and we approve a SIP that meets these requirements. Disapproval does not start a mandatory sanctions clock for Texas pursuant to CAA section 179 because this action does not pertain to a part D plan for nonattainment areas required under CAA section 110(a)(2)(I) or a SIP call pursuant to CAA section 110(k)(5).

IV. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This final action is not a "significant regulatory action" and was therefore not submitted to the Office of Management and Budget for review.

B. Paperwork Reduction Act (PRA)

This final action does not impose an information collection burden under the PRA because it does not contain any information collection activities.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action merely disapproves a SIP submittal as not meeting certain CAA requirements.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. This action does not apply on any Indian reservation land, any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction, or non-reservation areas of Indian country. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it merely disapproves a SIP submittal as not meeting certain CAA requirements.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes the human health or environmental risk addressed by this action will not have potential disproportionately high and adverse human health or environmental effects on minority, low-income or indigenous populations. This action merely disapproves a SIP submittal as not meeting certain CAA requirements.

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 11, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See CAA section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Ozone.

Dated: August 1, 2016.

Ron Curry,

Regional Administrator, Region 6.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart SS—Texas

■ 2. Section 52.2275 is amended by adding paragraph (l) to read as follows:

§ 52.2275 Control strategy and regulations: Ozone.

* * * * *

(l) The portion of the SIP submitted on December 13, 2012 addressing Clean Air Act section 110(a)(2)(D)(i)(I) for the 2008 ozone NAAQS is disapproved.

[FR Doc. 2016–19151 Filed 8–11–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R10–OAR–2015–0397; FRL–9950–58–Region 10]

Approval and Promulgation of Implementation Plans; Idaho: Stationary Source Permitting Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving, and incorporating by reference, revisions to

the Idaho State Implementation Plan (SIP) submitted on May 21, 2015. In the submission, Idaho revised stationary source permitting rules, including the addition of facility-wide emission limits and nonmetallic mineral processing plant regulations. Idaho also added an alternative method for stationary sources to comply with sulfur content of fuels limits, and updated provisions to account for changes to federal air quality regulations. The EPA is approving the submitted revisions, with the exception of certain provisions that are inappropriate for SIP approval.

DATES: This final rule is effective September 12, 2016.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R10–OAR–2015–0397. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information may not be publicly available, *i.e.,* Confidential Business Information or other information the disclosure of which is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and is publicly available only in hard copy form. Publicly available docket materials are available at *http://www.regulations.gov* or at EPA Region 10, Office of Air and Waste, 1200 Sixth Avenue, Seattle, Washington 98101. The EPA requests that you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding federal holidays.

FOR FURTHER INFORMATION CONTACT: Kristin Hall, Air Planning Unit, Office of Air and Waste (AWT–150), Environmental Protection Agency—Region 10, 1200 Sixth Ave., Seattle, WA 98101; telephone number: (206) 553–6357; email address: *hall.kristin@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document wherever "we," "us," or "our" is used, it is intended to refer to the EPA.

Table of Contents

I. Background
II. Final Action
III. Incorporation by Reference
IV. Statutory and Executive Orders Review

I. Background

On May 21, 2015, Idaho submitted revisions to the Idaho State Implementation Plan. On June 19, 2016, the EPA proposed to approve the submitted revisions, with the exception of certain provisions that are inappropriate for SIP approval (81 FR 37170). Please see our proposed rulemaking for further explanation and the basis for our finding. The public comment period for this proposal ended on July 11, 2016. We received no comments on the proposal.

II. Final Action

The EPA is approving, and incorporating by reference, the following revisions to the Idaho SIP submitted on May 21, 2015:

- IDAPA 58.01.01.006 *General Definitions,* except .49, .50, .51, .66, .67, .68.b, .116 (renumbered from .114), and .118 (renumbered from .116) (State effective 4/11/2014);
- IDAPA 58.01.01.011 *Definitions for the Purposes of Sections 790 through 799* (State effective 3/15/2002);
- IDAPA 58.01.01.107 *Incorporations by Reference,* except .03.f through .n, and with respect to .a, the incorporation by reference of 40 CFR 51.165 (State effective 4/11/2015);
- IDAPA 58.01.01.157 *Test Methods and Procedures* (State effective 4/11/2015);
- IDAPA 58.01.01.175 *Procedures and Requirements for Permits Establishing a Facility Emissions Cap* (State effective 4/11/2015);
- IDAPA 58.01.01.176 *Facility Emissions Cap,* except for provisions relating to hazardous air pollutants (State effective 4/11/2015);
- IDAPA 58.01.01.177 *Application Procedures* (State effective 4/11/2015);
- IDAPA 58.01.01.178 *Standard Contents of Permits Establishing a Facility Emissions Cap* (State effective 4/11/2015);
- IDAPA 58.01.01.179 *Procedures for Issuing Permits Establishing a Facility Emissions Cap* (State effective 4/11/2015);
- IDAPA 58.01.01.180 *Revisions to Permits Establishing a Facility Emissions Cap* (State effective 4/11/2015);
- IDAPA 58.01.01.181 *Notice and Record-Keeping of Estimates of Ambient Concentrations* (State effective 4/11/2015);
- IDAPA 58.01.01.201 *Permit to Construct Required* (State effective 4/11/2006);
- IDAPA 58.01.01.202 *Application Procedures* (State effective 4/11/2015);
- IDAPA 58.01.01.401 *Tier II Operating Permit,* except .01.a and .04, (State effective 4/11/2006);
- IDAPA 58.01.01.579 *Baselines for Prevention of Significant Deterioration* (State effective 4/11/2015);
- IDAPA 58.01.01.725 *Rules for Sulfur Content of Fuels* (State effective 4/11/2015);
- IDAPA 58.01.01.790 *Rules for the Control of Nonmetallic Mineral Processing Plants* (State effective 3/15/2002);
- IDAPA 58.01.01.791 *General Control Requirements,* (State effective 3/15/2002);
- IDAPA 58.01.01.793 *Emissions Standards for Nonmetallic Mineral Processing Plants not Subject to 40 CFR 60, Subpart OOO* (State effective 3/15/2002);
- IDAPA 58.01.01.794 *Permit Requirements,* except .04 (State effective 4/11/2015);
- IDAPA 58.01.01.795 *Permit by Rule Requirements* (State effective 3/15/2002);
- IDAPA 58.01.01.796 *Applicability* (State effective 3/15/2002);
- IDAPA 58.01.01.797 *Registration for Permit by Rule* (State effective 3/15/2002);
- IDAPA 58.01.01.798 *Electrical Generators* (State effective 3/15/2002); and
- IDAPA 58.01.01.799 *Nonmetallic Mineral Processing Plan Fugitive Dust Best Management Practice* (State effective 3/15/2002).

III. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference as described in the amendments to 40 CFR part 52 set forth below. These materials have been approved by the EPA for inclusion in the State Implementation Plan, have been incorporated by reference by the EPA into that plan, are fully federally-enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of the EPA's approval, and will be incorporated by reference by the Director of the Federal Register in the next update to the SIP compilation.[1] The EPA has made, and will continue to make, these materials generally available through *http://www.regulations.gov* and/or at the EPA Region 10 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble).

IV. Statutory and Executive Orders Review

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the

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[1] 62 FR 27968 (May 22, 1997).

EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because this action does not involve technical standards; and
- does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian Tribe has demonstrated that a Tribe has jurisdiction. In those areas of Indian country, the rule does not have Tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 11, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (*See* section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: July 25, 2016.

Dennis J. McLerran,

Regional Administrator, Region 10.

For the reasons set forth in the preamble, 40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart N—Idaho

■ 2. In § 52.670, the table in paragraph (c) is amended by:

■ a. Revising entries 006, 107, 157, 201, 202, 401, 579, and 725.

■ b. Adding entries 011, 175, 176, 177, 178, 179, 180, 181, 790, 791, 793, 794, 795, 796, 797, 798, and 799 in numerical order.

The revisions and additions read as follows:

§ 52.670 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED IDAHO REGULATIONS AND STATUTES

State citation	Title/subject	State effective date	EPA approval date	Explanations
Idaho Administrative Procedures Act (IDAPA) 58.01.01—Rules for the Control of Air Pollution in Idaho				
*	*	* *	*	* *
006	General Definitions	4/11/2015, 4/4/2013, 3/30/2007, 4/11/2006, 7/1/2002, 4/5/2000, 3/20/1997, 5/1/1994.	8/12/2016, [Insert **Federal Register** citation].	Except Section 006.49, 006.50, 006.51, 006.66, 006.67, 006.68.b, 006.116, and 006.118.
*	*	* *	*	* *
011	Definitions for the Purposes of Sections 790 through 799.	3/15/2002	8/12/2016, [Insert **Federal Register** citation].	
*	*	* *	*	* *
107	Incorporation by Reference	4/11/2015, 3/20/2014, 3/30/2007, 7/1/1997, 5/1/1994.	8/12/2016, [Insert **Federal Register** citation].	Except Section 107.03.f through 107.03.p.

EPA-APPROVED IDAHO REGULATIONS AND STATUTES—Continued

State citation	Title/subject	State effective date	EPA approval date	Explanations
*	*	* *	*	* *
157	Test Methods and Procedures	4/11/2015	8/12/2016, [Insert **Federal Register** citation].	
*	*	* *	*	* *
175	Procedures and Requirements for Permits Establishing a Facility Emissions Cap.	4/11/2015	8/12/2016, [Insert **Federal Register** citation].	
176	Facility Emissions Cap	4/11/2015	8/12/2016, [Insert **Federal Register** citation].	Except for provisions relating to hazardous air pollutants.
177	Application Procedures	4/11/2015	8/12/2016, [Insert **Federal Register** citation].	
178	Standard Contents of Permits Establishing a Facility Emissions Cap.	4/11/2015	8/12/2016, [Insert **Federal Register** citation].	
179	Procedures for Issuing Permits Establishing a Facility Emissions Cap.	4/11/2015	8/12/2016, [Insert **Federal Register** citation].	
180	Revisions to Permits Establishing a Facility Emissions Cap.	4/11/2015	8/12/2016, [Insert **Federal Register** citation].	
181	Notice and Record-Keeping of Estimates of Ambient Concentrations.	4/11/2015	8/12/2016, [Insert **Federal Register** citation].	
*	*	* *	*	* *
201	Permit to Construct Required	4/11/2006	8/12/2016, [Insert **Federal Register** citation].	
202	Application Procedures	4/11/2015	8/12/2016, [Insert **Federal Register** citation].	
*	*	* *	*	* *
401	Tier II Operating Permit	4/11/2015	8/12/2016, [Insert **Federal Register** citation].	Except Section 401.01.a and 401.04.
*	*	* *	*	* *
579	Baselines for Prevention of Significant Deterioration.	4/11/2015	8/12/2016, [Insert **Federal Register** citation].	
*	*	* *	*	* *
725	Rules for Sulfur Content of Fuels	4/11/2015	8/12/2016, [Insert **Federal Register** citation].	
*	*	* *	*	* *
790	Rules for the Control of Nonmetallic Mineral Processing Plants.	3/15/2002	8/12/2016, [Insert **Federal Register** citation].	
791	General Control Requirements	3/15/2002	8/12/2016, [Insert **Federal Register** citation].	
793	Emissions Standards for Nonmetallic Mineral Processing Plants not Subject to 40 CFR 60, Subpart OOO.	3/15/2002	8/12/2016, [Insert **Federal Register** citation].	
794	Permit Requirements	4/11/2015	8/12/2016, [Insert **Federal Register** citation].	Except Section 794.04.
795	Permit by Rule Requirements	3/15/2002	8/12/2016, [Insert **Federal Register** citation].	

EPA-APPROVED IDAHO REGULATIONS AND STATUTES—Continued

State citation	Title/subject	State effective date	EPA approval date	Explanations
796	Applicability	3/15/2002	8/12/2016, [Insert **Federal Register** citation].	
797	Registration for Permit by Rule	3/15/2002	8/12/2016, [Insert **Federal Register** citation].	
798	Electrical Generators	3/15/2002	8/12/2016, [Insert **Federal Register** citation].	
799	Nonmetallic Mineral Processing Plan Fugitive Dust Best Management Practice.	3/15/2002	8/12/2016, [Insert **Federal Register** citation].	
*	*	*	*	*

* * * * *

■ 3. Section 52.683 is amended by revising paragraph (a) to read as follows:

§ 52.683 Significant deterioration of air quality.

(a) The State of Idaho Rules for Control of Air Pollution in Idaho, specifically, IDAPA 58.01.01.005 through 007 (definitions), IDAPA 58.01.01.107.03.a, .b, .c (incorporations by reference), IDAPA 58.01.01.200 through 222 (permit to construct rules); IDAPA 58.01.01.510 through 516 (stack height rules); and IDAPA 58.01.01.575 through 581 (standards, increments and area designations) (except IDAPA 58.01.01.577), are approved as meeting the requirements of title I, part C, subpart 1 of the Clean Air Act for preventing significant deterioration of air quality.

* * * * *

[FR Doc. 2016–19122 Filed 8–11–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2015–0711; FRL–9949–84–Region 9]

Approval and Promulgation of Implementation Plans; California; San Joaquin Valley; Revisions to Motor Vehicle Emissions Budgets for Ozone and Particulate Matter

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve and conditionally approve revisions to the State of California's State Implementation Plan (SIP) for the San Joaquin Valley (SJV) area. The revisions consist of an update to the Motor Vehicle Emissions Budgets ("budgets") for nitrogen oxides (NO_X) and volatile organic compounds (VOCs) for the 1997 8-hour ozone national ambient air quality standard (NAAQS or "standard") for the SJV ozone nonattainment area and for NO_X and coarse particulate matter (PM_{10}) for the 1987 24-hour PM_{10} standard for the SJV PM_{10} maintenance area. The EPA is approving the SJV ozone revised budgets and conditionally approving the PM_{10} budgets in accordance with the requirements of the Clean Air Act (CAA or "Act") and the EPA's regulations.

DATES: This rule is effective on September 30, 2016.

ADDRESSES: The EPA has established a docket for this action under Docket ID Number EPA–R09–OAR–2015–0711. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *e.g.,* confidential business information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *http://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: John Ungvarsky, Air Planning Office (AIR–2), U.S. Environmental Protection Agency, Region 9, (415) 972–3963, *ungvarsky.john@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, "we," "us" and "our" refer to the EPA.

Table of Contents

I. Proposed Action
II. Public Comments
III. Final Action
IV. Statutory and Executive Order Reviews

I. Proposed Action

On May 18, 2016 (81 FR 31212), the EPA proposed, under section 110(k)(3) of the Clean Air Act (CAA or "Act"), to approve a revision to the California SIP submitted by the California Air Resources Board (CARB) on November 13, 2015.[1] The SIP submittal revises budgets applicable to control strategy or maintenance plans for the SJV for the 1997 8-hour ozone standard, 2006 24-hour $PM_{2.5}$ standard, and the 1987 24-hour PM_{10} standard.[2] In our May 18, 2016 action, we proposed to approve revised budgets for the 1997 8-hour ozone standard and the 2006 24-hour $PM_{2.5}$ standard. We also proposed to conditionally approve revised budgets for the 1987 24-hour PM_{10} standard. CARB developed the revised budgets using EMFAC2014 and the travel activity projections provided by the SJV Metropolitan Planning Organizations (MPOs) consistent with the 2015 Federal Transportation Improvement Program (TIP). As such, the revised budgets reflect the most recent planning forecasts and are based on the most recent emission factor data and approved calculation methods.

The EPA previously approved the SJV budgets for the 1997 8-hour ozone standard and the 24-hour PM_{10} standard. The ozone budgets were included in the EPA's approval of the SJV 2007 8-hour Ozone Plan ("2007 Ozone Plan") at 77 FR 12652 (March 1, 2012), which established NO$_X$ and VOC[3] budgets for 2011, 2014, 2017, 2020, and 2023.[4] The PM$_{10}$ budgets were included in the EPA's approval of the 2007 PM$_{10}$ Maintenance Plan and Request for Redesignation ("2007 PM$_{10}$ Plan") at 73 FR 66759 (November 12, 2008), which established direct PM$_{10}$ and NO$_X$ budgets for 2005 and 2020.[5] The SJV budgets for the 2006 24-hour PM$_{2.5}$ standard were included in the EPA's proposed approval of the SJV 2012 PM$_{2.5}$ Plan ("2012 PM$_{2.5}$ Plan") at 80 FR 1816 (January 13, 2015). The EPA found the 2017 PM$_{2.5}$ budgets in the SJV 2012 PM$_{2.5}$ Plan to be adequate at 81 FR 22194 (April 15, 2016), establishing direct PM$_{2.5}$ and NO$_X$ budgets for 2017. As of May 2, 2016, these budgets must be used to determine conformity of transportation plans and TIPs to the control strategy plan for the SJV for the 2006 24-hour PM$_{2.5}$ standard.[6]

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[1] Letter, Richard W. Corey, Executive Officer, CARB to Jared Blumenfeld, Regional Administrator, EPA Region 9, November 13, 2015 with enclosures.

[2] For all three pollutants, the SJV nonattainment area includes all of seven counties, including Fresno, Kings, Madera, Merced, San Joaquin, Stanislaus, and Tulare counties, and the western half of Kern County. See the NAAQS-specific tables in 40 CFR 81.305.

In our May 18, 2016 proposed rule, we reviewed the revised budgets for the 1997 8-hour ozone standard in the November 13, 2015 submittal, evaluated them for compliance with statutory and regulatory requirements, and concluded that they meet all applicable requirements. More specifically, under CAA section 110(k)(3), we proposed to approve the revised VOC and NO$_X$ budgets in table 1 for 2017, 2020, and 2023 for the 1997 8-hour ozone standard. We determined that replacement of the current approved budgets with the revised VOC and NO$_X$ budgets would not interfere with the approved RFP and attainment demonstrations for the 1997 8-hour ozone standard in the SJV and emissions changes in non-motor vehicle emissions categories do not change the overall conclusions of the 2007 Ozone Plan.

TABLE 1—SAN JOAQUIN VALLEY REVISED BUDGETS DEVELOPED FOR THE 1997 8-HOUR OZONE STANDARD USING EMFAC2014[7] [8]

County subarea	NO$_X$ (tons per summer day)			VOC (tons per summer day)		
	2017	2020	2023	2017	2020	2023
Fresno	29.9	24.3	14.6	8.7	6.8	5.6
Kern (SJV)	26.8	22.4	12.9	6.9	5.7	4.8
Kings	5.5	4.7	2.7	1.4	1.1	0.9
Madera	5.5	4.5	2.7	2.0	1.6	1.3
Merced	10.3	8.5	5.1	2.7	2.1	1.7
San Joaquin	14.1	11.3	7.3	6.4	5.1	4.3
Stanislaus	11.3	9.2	5.8	4.1	3.2	2.7
Tulare	10.3	8.1	4.9	4.0	3.1	2.5

Second, under CAA section 110(k)(4), the EPA proposed to conditionally approve the revised direct PM$_{10}$ and NO$_X$ budgets in table 2 for 2020 for the 24-hour PM$_{10}$ standard. We determined that, when combined with implementation of the contingency plan in the SIP-approved 2007 PM$_{10}$ Plan and fulfillment of the commitments in the State's April 29, 2016 letter, the revised direct PM$_{10}$ and NO$_X$ budgets will allow the SJV to continue to demonstrate maintenance of the 24-hour PM$_{10}$ standard. The contents of the State's April 29, 2016 letter are described in detail in our proposed rule on pages 31220 and 31221. In our proposal, we explained that if the conditional approval is finalized, CARB must adopt and submit the SIP revisions that it has committed to submit by June 1, 2017. The resulting impacts if CARB fails to comply with this commitment are explained below in section III of today's action.

TABLE 2—SAN JOAQUIN VALLEY REVISED 2020 BUDGETS FOR THE PM$_{10}$ STANDARD DEVELOPED USING EMFAC2014[9] [10]

County subarea	Direct PM$_{10}$ (tons per annual day)	NO$_X$ (tons per annual day)
Fresno	7.0	25.4
Kern (SJV)	7.4	23.3
Kings	1.8	4.8
Madera	2.5	4.7
Merced	3.8	8.9
San Joaquin	4.6	11.9
Stanislaus	3.7	9.6
Tulare	3.4	8.4

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[3] California plans sometimes use the term Reactive Organic Gases (ROG) for VOC. These terms are essentially synonymous. For simplicity, we use the term VOC herein to mean either VOC or ROG.

[4] The approved 2007 Ozone Plan includes the SJV 2007 Ozone Plan (as revised 2008 and 2011) and SJV-related portions of CARB's 2007 State Strategy (revised 2009 and 2011).

[5] The approved SIP includes the 2007 PM$_{10}$ Maintenance Plan and Request for Redesignation, September 20, 2007, and technical corrections by CARB to the 2020 budgets for Merced, San Joaquin, Stanislaus and Tulare counties in the 2007 PM$_{10}$ Plan. See May 13, 2008 letter to Wayne Nastri from James N. Goldstene.

[6] Also see letter, Elizabeth J. Adams, Deputy Director, Air Division, EPA Region 9, to Richard W. Corey, Executive Officer, CARB, April 1, 2016 with enclosures.

[7] The county-specific budgets are set forth in attachment A to CARB Resolution 15–50. Attachment A constitutes the SIP revision adopted by CARB on October 22, 2015 and submitted on November 13, 2015. CARB provided information and analysis supporting the SIP revision in a staff report titled *Updated Transportation Conformity Budgets for the San Joaquin Valley Ozone, PM$_{2.5}$, and PM$_{10}$ State Implementation Plans*, release date September 21, 2015.

[8] CARB calculated the revised budgets for the SJV plans by taking the sum of the county-by-county emissions results from EMFAC and rounding the SJV-wide total up to the nearest whole ton for NO$_X$ and to the nearest tenth of a ton for VOC and PM$_{10}$; then re-allocating to the individual counties based on the ratio of each county's contribution to the total; and then rounding each county's emissions to the nearest tenth of a ton using the conventional rounding method.

[9] The county-specific budgets are set forth in attachment A to CARB Resolution 15–50. Attachment A constitutes the SIP revision adopted by CARB on October 22, 2015 and submitted on November 13, 2015. CARB provided information and analysis supporting the SIP revision in a staff report titled *Updated Transportation Conformity Budgets for the San Joaquin Valley Ozone, PM$_{2.5}$, and PM$_{10}$ State Implementation Plans*, release date September 21, 2015.

[10] CARB calculated the revised budgets for the SJV plans by taking the sum of the county-by-county emissions results from EMFAC and

Continued

Third, the EPA also proposed to approve the revised direct $PM_{2.5}$ and NO_X budgets for 2017 for the 2006 24-hour $PM_{2.5}$ standard. We determined that: (1) Replacement of the current adequate budgets with the revised budgets would be consistent with our separate proposal finding that the 2012 $PM_{2.5}$ Plan demonstrates RFP for year 2017; (2) emissions changes in non-motor vehicle emissions categories do not change the overall conclusion of the 2012 $PM_{2.5}$ Plan; and (3) the revised budgets meet the adequacy criteria in 40 CFR 93.118(e)(4)(i)–(vi). Because the EPA has yet to finalize its approval of 2012 $PM_{2.5}$ Plan, we are not able to finalize, in today's action, our approval of the revised direct $PM_{2.5}$ and NO_X budgets for 2017 in CARB's submittal dated November 13, 2015 for the 2006 24-hour $PM_{2.5}$ standard. The EPA expects to take final action on the revised $PM_{2.5}$ budgets for 2017 as part of its final action on the 2012 $PM_{2.5}$ Plan for the 2006 24-hour $PM_{2.5}$ standard.

Lastly, on the effective date of today's action, the previously-approved budgets for the 1997 8-hour ozone standard and the 1987 24-hour PM_{10} standard would no longer be applicable for transportation conformity purposes, and the SJV MPOs and the U.S. Department of Transportation (DOT) must use the revised budgets for future transportation conformity determinations.

Please see our May 18, 2016 proposed rule for more information concerning the background for this action and for a more detailed discussion of the rationale for approval of the revised budgets.

II. Public Comments

Our May 18, 2016 proposed rule provided a 30-day public comment period, which closed on June 17, 2016. We received no comments on our proposal during this period.

III. Final Action

For the reasons discussed in the May 18, 2016 proposed rule and summarized above, the EPA is approving, or conditionally approving, revised motor vehicle emissions budgets submitted on November 13, 2015 by CARB for the SJV area as a revision to the California SIP. More specifically, the EPA is approving, under CAA section 110(k)(3), revised VOC and NO_X budgets shown in table 1 above for 2017, 2020, and 2023 for the 1997 8-hour ozone standard. The EPA is conditionally approving, under CAA section 110(k)(4), the revised direct PM_{10} and NO_X budgets shown in table 2 above for 2020 for the 24-hour PM_{10} standard. CARB must adopt and submit the SIP revisions that it has committed to submit by June 1, 2017, as described in their April 29, 2016 letter. If CARB fails to comply with this commitment, the conditional approval will convert to a disapproval. Disapproval of the revised budgets for the 2007 PM_{10} Plan would reinstate the existing approved budgets as the budgets that must be used in transportation plan and TIP conformity determinations after the effective date of the disapproval. See 40 CFR 93.109(c)(1).[11]

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve State choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves revisions to motor vehicle emission budgets as meeting Federal requirements and does not impose additional requirements beyond those imposed by State law. For that reason, this action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide the EPA with the discretionary authority to address disproportionate human health or environmental effects with practical, appropriate, and legally permissible methods under Executive Order 12898 (59 FR 7629, February 16, 1994).

Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), requires the EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have Tribal implications" is defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian Tribes."

Eight Indian tribes are located within the boundaries of the SJV air quality planning area for the 1997 8-hours ozone standard and 24-hour PM_{10} standard: The Big Sandy Rancheria of Mono Indians of California, the Cold Springs Rancheria of Mono Indians of California, the North Fork Rancheria of Mono Indians of California, the Picayune Rancheria of Chukchansi Indians of California, the Santa Rosa Rancheria of the Tachi Yokut Tribe, the Table Mountain Rancheria of California, the Tejon Indian Tribe, and the Tule River Indian Tribe of the Tule River Reservation.

The EPA's approval into the SIP of the SJV revised budgets submitted by CARB would not have tribal implications because the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the SIP approvals do not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65

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rounding the SJV-wide total up to the nearest whole ton for NO_X and to the nearest tenth of a ton for VOC and PM_{10}; then re-allocating to the individual counties based on the ratio of each county's contribution to the total; and then rounding each county's emissions to the nearest tenth of a ton using the conventional rounding method.

[11] Because the submittal of the revised budgets is not a required submittal, disapproval would not trigger sanctions under CAA section 179(a)(2) but would nonetheless trigger a two-year clock for a federal implementation plan under CAA section 110(c). Disapproval would not trigger a transportation conformity freeze because the disapproval does not affect a control strategy implementation plan as defined in the transportation conformity rule. See 40 CFR 93.101 and 93.120(a).

FR 67249, November 9, 2000). Therefore, the EPA has concluded that the action will not have tribal implications for the purposes of Executive Order 13175, and will not impose substantial direct costs upon the tribes, nor will it preempt Tribal law. We note that none of the tribes located in the SJV has requested eligibility to administer programs under the CAA.

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 11, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (*See* section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental regulations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur dioxide, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: July 8, 2016.

Alexis Strauss,

Acting Regional Administrator, EPA Region 9.

Chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraph (c)(476) to read as follows:

§ 52.220 Identification of plan—in part.

* * * * *

(c) * * *

(476) The following revision was submitted on November 13, 2015 by the Governor's designee.

(i) [Reserved]

(ii) Additional materials.

(A) California Air Resources Board.

(*1*) Attachment A to Resolution 15–50, "Updates to the Transportation Conformity Budgets for the San Joaquin Valley 2007 PM_{10}, 2007 Ozone and 2012 $PM_{2.5}$ SIPs," Table A–1 (Updated Transportation Conformity Budgets for the 2008 Ozone Plan (Tons per summer day) and Table A–3 (Updated Transportation Conformity Budgets for the 2008 PM_{10} Maintenance Plan (Tons per annual day)).

* * * * *

■ 3. Subpart F is amended by adding § 52.248 to read as follows:

§ 52.248 Identification of plan—conditional approval.

The EPA is conditionally approving a California State Implementation Plan (SIP) revision submitted on November 13, 2015 updating the motor vehicle emissions budgets for nitrogen oxides (NO_X) and coarse particulate matter (PM_{10}) for the 1987 24-hour PM_{10} standard for the San Joaquin Valley PM_{10} maintenance area. The conditional approval is based on a commitment from the State to submit a SIP revision that demonstrates full implementation of the contingency provisions of the 2007 PM_{10} Maintenance Plan and Request for Redesignation (September 20, 2007). If the State fails to meets its commitment by June 1, 2017, the approval is treated as a disapproval.

[FR Doc. 2016–18898 Filed 8–11–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2015–0724; FRL–9950–52–Region 5]

Air Plan Approval; Indiana; Abengoa Bioenergy of Indiana, Commissioner's Order

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a revision to the Indiana State Implementation Plan (SIP) submitted by the Indiana Department of Environmental Management (IDEM) on October 16, 2015. The submittal consists of an order issued by the Commissioner of IDEM (Commissioner's Order No. 2015–01) approving alternative control technology requirements for Abengoa Bioenergy of Indiana (Abengoa). These requirements include the use of a carbon adsorption/absorption hydrocarbon vapor recovery system with a minimum overall control efficiency of 98% to control volatile organic compound (VOC) emissions from the ethanol loading racks at Abengoa. A continuous emissions monitoring system (CEMS) must be used to monitor the carbon adsorption/absorption hydrocarbon vapor recovery system for breakthrough of VOC emissions. For the reasons discussed below, EPA is approving this submittal as a revision to Indiana's SIP.

DATES: This direct final rule will be effective October 11, 2016, unless EPA receives adverse comments by September 12, 2016. If adverse comments are received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2015–0724, at *http://www.regulations.gov* or via email to *aburano.douglas@epa.gov*. For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the "For Further Information Contact" section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT:

Jenny Liljegren, Physical Scientist, Attainment Planning and Maintenance Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–6832, *Liljegren.Jennifer@epa.gov.*

SUPPLEMENTARY INFORMATION:

Throughout this document whenever "we," "us," or "our" is used, we mean EPA. This supplementary information section is arranged as follows:

I. What SIP revision is Indiana requesting and why?
II. What action is EPA taking and why?
III. Incorporation by Reference.
IV. Statutory and Executive Order Reviews.

I. What SIP revision is Indiana requesting and why?

IDEM requested on October 16, 2015, that EPA approve as a revision to the SIP alternative control technology requirements for Abengoa. These requirements include the use of a carbon adsorption/absorption hydrocarbon vapor recovery system with a minimum overall control efficiency of 98% to control VOC emissions from the ethanol loading racks at Abengoa. A CEMS must be used to monitor the carbon adsorption/absorption hydrocarbon vapor recovery system for breakthrough of VOC emissions. These requirements are contained in Commissioner's Order No. 2015–01 issued by the IDEM Commissioner on September 8, 2015.

In Abengoa's initial construction and operating permit issued by IDEM, the ethanol loading racks were subject to the statewide case-by-case Best Available Control Technology (statewide BACT) determination required under SIP-approved Title 326 Article 8 Rule 1–6 of the Indiana Administrative Code (326 IAC 8–1–6). The statewide BACT for Abengoa's ethanol loading racks was determined to be enclosed flares with a minimum overall control efficiency of 98%. Since then, Abengoa has modified its plant design, including the ethanol loading racks, and is now subject to a newer SIP-approved state rule, 326 IAC 8–5–6, Fuel Grade Ethanol Production at Dry Mills, which created an industry-specific statewide BACT standard and which replaced the statewide case-by-case BACT rule (326 IAC 8–1–6) for fuel grade ethanol production dry mills that have no wet milling operations. EPA approved this rule into the SIP on February 20, 2008 (73 FR 9201).

The three VOC control options under 326 IAC 8–5–6 are: (1) A thermal oxidizer with a minimum overall control efficiency of 98% or resulting in a VOC concentration of not more than ten (10) parts per million (ppm), (2) a wet scrubber with a minimum overall control efficiency of 98% or resulting in a VOC concentration of not more than twenty (20) ppm, and (3) an enclosed flare with a minimum overall control efficiency of 98%. The VOC control options under 326 IAC 8–5–6 do not include a carbon adsorption/absorption hydrocarbon vapor recovery system. Abengoa has opted to use a carbon adsorption/absorption hydrocarbon vapor recovery system rather than one of the VOC control options under 326 IAC 8–5–6. However, like the VOC control options under 326 IAC 8–5–6, Abengoa's carbon adsorption/absorption system has a minimum overall control efficiency of 98%. IDEM considers the system Reasonably Available Control Technology (RACT) under SIP rule 326 IAC 8–1–5 (Petition for a site-specific reasonably available control technology (RACT) plan).

As a result, pursuant to 326 IAC 8–1–5, Indiana has issued Commissioner's Order No. 2015–01 approving Abengoa's use of this system as an alternative site-specific RACT in lieu of the industry-specific statewide BACT options under 326 IAC 8–5–6. The carbon adsorption/absorption system will control VOC emissions at a minimum overall control efficiency of 98%, which is the same level of control of the industry-specific BACT options under 326 IAC 8–5–6; therefore, there will be no relaxation of the emission reduction requirements at Abengoa as a result of this SIP revision. As an added benefit, Abengoa's use of the carbon adsorption/absorption system is expected to result in fewer criteria air pollutant emissions, since, unlike enclosed flares, carbon adsorption/absorption does not involve the combustion of natural gas.

It should be noted that Condition #3 of the "Conditions of Approval" in Commissioner's Order 2015–01 states: "The overall efficiency for the carbon adsorption/absorption hydrocarbon vapor recovery system (C–2101), including the capture efficiency and adsorption/absorption efficiency, shall be at least 98%. The Petitioner shall demonstrate compliance using methods approved by the department. Testing shall be conducted in accordance with the provisions of 326 IAC 3–6 (Source Sampling Procedures)". IDEM has confirmed in an email to EPA dated June 6, 2016, that this provision requires testing using EPA Method 25 (40 CFR part 60, appendix A–7).

II. What action is EPA taking and why?

EPA is approving the requirements in Commissioner's Order No. 2015–01 as a revision to the Indiana SIP. This is based on EPA's finding that the 98% minimum overall control efficiency adsorption/absorption system with a CEMS qualifies as alternative site-specific RACT under 326 IAC 8–1–5 of the Indiana SIP for Abengoa's ethanol loading racks. EPA also finds that this system constitutes statewide BACT under 326 IAC 8–1–6 of the Indiana SIP in lieu of the industry-specific statewide BACT options under 326 IAC 8–5–6 of the Indiana SIP. There will be no relaxation of the emission reduction requirements at Abengoa as a result of this SIP revision. Since this is not a relaxation, section 110(l) of the Clean Air Act (CAA) is satisfied and no backsliding is occurring as a result of this SIP revision. As an added benefit, Abengoa's use of the carbon adsorption/absorption system is expected to result in fewer criteria air pollutant emissions, since, unlike enclosed flares, carbon adsorption/absorption does not involve the combustion of natural gas.

We are publishing this action without prior proposal because we view this as a noncontroversial amendment and anticipate no adverse comments. However, in the proposed rules section of this **Federal Register** publication, we are publishing a separate document that will serve as the proposal to approve the state plan if relevant adverse written comments are filed. This rule will be effective October 11, 2016 without further notice unless we receive relevant adverse written comments by September 12, 2016. If we receive such comments, we will withdraw this action before the effective date by publishing a subsequent document that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on the proposed action. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. If we do not receive any comments, this action will be effective October 11, 2016.

III. Incorporation by Reference

In this rule, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of the Indiana Regulations described in the amendments to 40 CFR part 52 set forth below. Therefore, these materials have been approved by EPA for inclusion in the State implementation plan, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference by the Director of the Federal Register in the next update to the SIP compilation.[1] EPA has made, and will continue to make, these documents generally available through *www.regulations.gov* and/or at the EPA Region 5 Office (please contact the person identified in the "For Further Information Contact" section of this preamble for more information.

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 11, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the proposed rules section of today's **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: August 1, 2016.

Robert A. Kaplan,

Acting Regional Administrator, Region 5.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

■ 2. In § 52.770 the table in paragraph (d) is amended by adding a new entry for "Abengoa Bioenergy of Indiana" to the end of the table, to read as follows:

§ 52.770 Identification of plan.

* * * * *

(d) * * *

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[1] 62 FR 27968 (May 22, 1997).

EPA-APPROVED INDIANA SOURCE-SPECIFIC PROVISIONS

CO date	Title	SIP rule	EPA approval	Explanation
*	*	*	*	*
9/8/2015	Abengoa Bioenergy of Indiana.	N.A	8/12/2016, [Insert **Federal Register** citation].	Alternative control technology requirements.

* * * * *

[FR Doc. 2016–19032 Filed 8–11–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2015–0489; FRL–9950–19–Region 9]

Revision to the California State Implementation Plan; San Joaquin Valley; Demonstration of Creditable Emission Reductions From Economic Incentive Programs

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is finalizing a limited approval and limited disapproval of a demonstration of creditable emission reductions submitted by California for approval into the San Joaquin Valley (SJV) portion of the California State Implementation Plan (SIP). This SIP submittal demonstrates that certain state incentive funding programs have achieved specified amounts of reductions in emissions of nitrogen oxides (NO_X) and fine particulate matter ($PM_{2.5}$) in the SJV area by 2014. The effect of this action would be to approve specific amounts of emission reductions for credit toward an emission reduction commitment in the California SIP. We are approving these emission reductions under the Clean Air Act (CAA or the Act).

DATES: This rule is effective on September 30, 2016.

ADDRESSES: The EPA has established docket number EPA–R09–OAR–2015–0489 for this action. Generally, documents in the docket for this action are available electronically at *http://www.regulations.gov* or in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California 94105–3901. While all documents in the docket are listed at *http://www.regulations.gov,* some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material, large maps, multi-volume reports), and some may not be available in either location (*e.g.,* confidential business information (CBI)). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Idalia Pérez, EPA Region IX, (415) 972 3248, *Perez.Idalia@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, "we," "us" and "our" refer to the EPA.

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I. Proposed Action
II. Public Comments and EPA Responses
III. EPA Action
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I. Proposed Action

On August 24, 2015 (80 FR 51147), the EPA proposed to approve the "Report on Reductions Achieved from Incentive-based Emission Reduction Measures in the San Joaquin Valley" (Emission Reduction Report) and, based on California's documentation therein of actions taken by grantees in accordance with the identified incentive program guidelines, to approve 7.8 tpd of NO_X emission reductions and 0.2 tpd of $PM_{2.5}$ emission reductions for credit toward the State's 2014 emission reduction commitments in its 2008 plan to provide for attainment of the 1997 $PM_{2.5}$ National Ambient Air Quality Standards (NAAQS) in the San Joaquin Valley (hereafter "2008 $PM_{2.5}$ Plan").[1] The California Air Resources Board (CARB) adopted the Emission Reduction Report on October 24, 2014 and submitted it to EPA as a revision to the California SIP on November 17, 2014. We proposed to approve the Emission Reduction Report based on a determination that it satisfied the applicable CAA requirements. Our proposed action contains more information on the Emission Reduction Report and our evaluation.

II. Public Comments and EPA Responses

The EPA's proposed action provided a 30-day public comment period. During this period, we received comments from Adenike Adeyeye, Earthjustice, by email dated and received September 16, 2015. The comments and our responses are summarized below.

Comment 1: Earthjustice asserts that the emission reductions identified in the Emission Reduction Report are not enforceable by the public and therefore should not be approved into the SIP. According to Earthjustice, the Carl Moyer program allows air districts to enter into emission reduction agreements with grant recipients, with CARB added to contracts as a third party with enforcement rights, but does not enable the public to enforce these emission reduction agreements entered into among CARB, the air district, and the grant recipient. Earthjustice argues that the EPA's enforceability criteria require that citizens have access to all emissions-related information obtained from participating sources and be able to file suit against a responsible entity for violations, and that the Emission Reduction Report does not meet these criteria.

Response 1: We agree with the commenter's statement that the public cannot enforce the agreements entered into among CARB, an air district and a grant recipient but disagree with the commenter's suggestion that this renders the Emission Reduction Report inconsistent with the EPA's enforceability criteria. This Emission Reduction Report was submitted to demonstrate that that a portion of the emission reductions required under a previously approved SIP commitment have in fact been achieved—not to satisfy a future emission reduction requirement—and thus it does not need to provide a citizen enforcement mechanism.

As we explained in our proposed rule, where a state relies on a discretionary economic incentive program (EIP) or other voluntary measure to satisfy an attainment planning requirement under the CAA (*e.g.,* to demonstrate that specific amounts of emission reductions will occur by a future milestone date), the state must take responsibility for assuring that SIP emission reduction requirements are met through an enforceable commitment, which becomes federally enforceable upon approval into the SIP. 80 FR 51147, 51150. Thus, had CARB submitted the Emission Reduction Report to satisfy a future emission reduction requirement under the CAA, an enforceable state commitment to assure that the required emission reductions occur would be necessary to satisfy the Act's enforceability requirements. The purpose of the Emission Reduction Report, however, is to demonstrate that a portion of the emission reductions required under a previously-approved SIP commitment have in fact been achieved, not to satisfy a future emission reduction requirement. *See id.* at 51150–51151. Accordingly, it is not necessary to require the State to submit, as part of this particular SIP submission, additional commitments to achieve future emission reductions.

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[1] The 2014 emission reduction commitments are codified at 40 CFR 52.220(c)(356)(ii)(B)(*2*) and 52.220(c)(392)(ii)(A)(*2*). 76 FR 69896, 69926 (November 9, 2011).

The EPA evaluated the Emission Reduction Report in accordance with the Agency's guidance on discretionary EIPs. *See* 80 FR 51147, 51149–50 (citing, *inter alia,* U.S. EPA, "Improving Air Quality with Economic Incentive Programs," January 2001 (hereafter "2001 EIP Guidance")). A discretionary EIP uses market-based strategies to encourage the reduction of emissions from stationary, area, and/or mobile sources in an efficient manner. *See* 2001 EIP Guidance at 3. To qualify for approval as a discretionary EIP, emission reductions or actions leading to reductions must be enforceable either by the State or by the EPA, and the State must be directly responsible for ensuring that program elements are implemented. *See id.* at 157–158 (states may use the 2001 EIP Guidance where "[a]ctions and/or emission reductions by identifiable sources are enforceable by [the State] and/or by the EPA").

A "financial mechanism EIP" is an EIP that indirectly reduces emissions by increasing costs for high emitting activities—*e.g.,* through subsidies targeted at promoting pollution-reducing activities or products. *See* 2001 EIP Guidance at 119–122. The EPA has identified several attributes that may make subsidy financial mechanism EIPs successful, including: (1) The relevant governmental body possesses legal authority to provide subsidies; (2) the subsidies address activities reasonably related to actual emissions or potential emissions; (3) where projected emission reductions are based on changes in behavior, methods for verifying that such reductions have taken place to the degree projected are generally accepted as unbiased and trustworthy; and (4) if needed, adequate penalty provisions are in place to ensure that the subsidy is used as expected. *See* 2001 EIP Guidance at 27 ("Attributes That Make Subsidy Financial Mechanism EIPs Successful").

As explained further in Response 2 below, the portions of the Proposition 1B: Goods Movement Emission Reduction Program (Prop 1B program) and Carl Moyer Memorial Air Quality Standards Attainment Program (Carl Moyer Program) guidelines discussed in the Emission Reduction Report are consistent with the EPA's recommendations for "financial mechanism EIPs" in the 2001 EIP Guidance. First, CARB and the District are directly responsible for ensuring that the Prop 1B program and Carl Moyer Program are implemented in accordance with State law. *See* 2010 Prop 1B guidelines at 1–4 ("Overview") and 2011 Carl Moyer Program Guidelines at Chapter 1 ("Program Overview"). Second, the incentive programs discussed in the Emission Reduction Report address actions reasonably related to actual air pollutant emissions, *e.g.,* by requiring grant recipients to purchase and operate newer, cleaner vehicles or equipment in place of older, more-polluting vehicles or equipment, subject to detailed contract requirements. Third, the relevant portions of the 2008 and 2010 Prop 1B guidelines and the 2005, 2008 and 2011 Carl Moyer Program Guidelines establish a number of methods for verifying that projected emission reductions have taken place through compliance with the terms and conditions of each funding contract. Finally, under the applicable guidelines, actions by grantees that lead to emission reductions are directly enforceable by the State and/or the District—*e.g.,* CARB and/or the District may assess fiscal penalties and take certain corrective actions where contract violations are identified. Consistent with the EPA's recommendations for "financial mechanisms EIPs," these provisions in the 2008 and 2010 Prop 1B guidelines and the 2005, 2008 and 2011 Carl Moyer Program Guidelines are adequate to ensure that program funds are used as expected—*i.e.,* to reduce emissions from higher-polluting vehicles and equipment by replacing them with newer, lower-polluting equipment and vehicles. Based on our more detailed evaluations of 11 randomly selected projects from among those listed in the Emission Reduction Report, we find that the projects identified in the Emission Reduction Report were implemented as required under the applicable program guidelines and achieved the emission reductions projected for those projects, with the exception of one source category. *See* Response 2.

In sum, although an enforceable state commitment would ordinarily be necessary for a SIP submission that relies on a discretionary EIP to satisfy CAA enforceability requirements, such a commitment is not necessary in this case because the Emission Reduction Report was not submitted to satisfy a future emission reduction requirement and, instead, demonstrates only that certain Prop 1B program and Carl Moyer Program incentive projects achieved specified amounts of emission reductions in the past. The portions of the Prop 1B program and Carl Moyer Program guidelines that apply to the identified incentive projects ensure that program funds are used as expected and that the EPA and citizens have access to all emissions-related information obtained from participating sources. Based on our review of the available project records for a subset of the projects identified in the Emission Reduction Report, we find that the identified projects achieved the necessary emission reductions, with the exception of one source category discussed further below. Therefore, it is not necessary for the Emission Reduction Report to provide a mechanism for citizen suits against a responsible entity.

Comment 2: Earthjustice argues that, based on the information presented in the Emission Reduction Report, citizens cannot even obtain the information necessary to quantify and verify emission reductions. For example, Earthjustice states that the total project life for each stationary and portable farm engine funded through the Carl Moyer program varies from two years to ten years and that project life varies, in part, because emission reductions cannot be counted as surplus after the compliance date for a regulation applicable to that project. Earthjustice states that CARB is required to ensure that emission reductions from projects are no longer counted as SIP-creditable emission reductions after that compliance date but argues that "[n]either EPA nor the public has any way of knowing whether or not these projects were counted during only the years in which they were surplus because CARB does not provide enough information to determine a project's compliance date."

According to Earthjustice, to determine whether the stationary and portable farm engine projects were counted only for the years during which they could be considered surplus, one would need to know: What type of engine was used as a replacement; the horsepower of the engine used as a replacement; tier of the original agricultural engine; and fleetwide particulate matter (PM) levels.

Response 2: We disagree with the commenter's claim that citizens cannot obtain the information necessary to quantify and verify emission reductions. As we explained in the technical support document supporting our proposed rule and as explained in further detail below, the emission reductions identified in the Emission Reduction Report can be independently verified and the public has access to emissions-related information due to several requirements in the 2008 and 2010 Prop 1B guidelines and the 2005, 2008 and 2011 Carl Moyer Program guidelines. *See* U.S. EPA Region 9, Air Division, "Technical Support Document for EPA's Notice of Proposed Rulemaking for the California State Implementation Plan, Report on Reductions Achieved from Incentive-Based Emission Reduction Measures in the San Joaquin Valley," August 2015 ("Proposal TSD") at 7–15. We discuss the relevant guideline provisions in more detail below.

First, actions required of grantees under the applicable portions of the Prop 1B and Carl Moyer Program guidelines are independently verifiable through (1) pre-project and post-project on-site inspections (with photographic documentation) that the District and/or CARB must carry out pursuant to the applicable guidelines, and (2) documents that each grantee is required to maintain and/or submit to the District in accordance with detailed contract provisions. *See generally* 2008 Prop 1B guidelines at Section III.D ("Local Agency Project Implementation Requirements"), Section IV ("General Equipment Project Requirements"), and Appendix A, Section C ("Recordkeeping Requirements") and Section D ("Annual Reporting Requirements"); 2010 Prop 1B guidelines at Section IV.A ("Project Implementation Requirements"), Section VI ("General Equipment Project Requirements"), and Appendix A, Section F ("Recordkeeping Requirements") and Section G ("Annual Reporting Requirements"); 2005 Carl Moyer Guidelines, Part I, Chapter 2 ("Administration of the Carl Moyer Program"); 2008 Carl Moyer Guidelines, Part III ("Program Administration") and 2011 Carl Moyer Program Guidelines, Part I, Chapter 3 ("Program Administration").

For example, the 2008 and 2010 Prop 1B guidelines require, among other things, that (1) all project applications include documentation of current equipment and activity information (*e.g.* engine make, model, horsepower and fuel type, annual vehicle miles of travel (VMT) in California, and estimated percentage of annual VMT in trade corridors); (2) that the District conduct a "pre-inspection" of each application deemed eligible for funding, to verify information regarding the baseline engine, vehicle, or equipment; (3) that the District conduct a "post-inspection" of each funded project to record, among other things, identifiers and specifications for the new engine/equipment (*e.g.,* Vehicle Identification Numbers (VIN) for new trucks, serial numbers for new engines), and verification that the new engine/equipment is operational and consistent with the old/replaced equipment, where applicable; and (4) that the District's pre-inspection and post-inspection project files include photographic documentation of each piece of equipment being inspected, including an engine serial number, visible distinguishing identification (*e.g.,* a license plate), and a full view of the equipment. *See* 2008 Prop 1B guidelines at Section III.D.8 ("Equipment project pre-inspections'), Section III.D.14 ("Equipment project post-inspections"), Section IV.D ("Equipment Project Application Requirements") and Appendix A, Section F ("Application Information"); 2010 Prop 1B guidelines at Section IV.A.10 ("Equipment project pre-inspections"), Section IV.A.16 ("Equipment project post-inspections"), Section VI.D ("Equipment Project Application Requirements") and Appendix A, Section F ("Application Information"); *see also* Proposal TSD at 14–15.

Similarly, the 2005, 2008 and 2011 Carl Moyer Program Guidelines require, among other things, that (1) all project applications include documentation of existing engine usage in previous years (*e.g.* miles traveled, hours operated, or fuel consumed per year); (2) that the District conduct a "pre-inspection" of each application deemed eligible for funding, to verify information regarding the baseline engine, vehicle, or equipment; (3) that the District conduct a "post-inspection" of each funded project to record, among other things, information regarding the new engines, vehicles/equipment, and retrofit devices as needed to provide a basis for emission calculations and to ensure contract enforceability; and (4) that the District's pre-inspection and post-project files include photographic documentation of the engine, vehicle, or equipment information, including a legible serial number and/or other identifying markings. *See* 2005 Carl Moyer Program Guidelines, Part I, Chapter 2 at Section V.D ("Project Applications"), Section IX.A ("Pre-Inspection"), and Section IX.B ("Post-Inspection"); 2008 Carl Moyer Program Guidelines, Part III, Part II at Section 26 ("Minimum Project Application Requirements"), Section 30 ("Project Pre-Inspections"), and Section 31 ("Post-Inspection"); 2011 Carl Moyer Program Guidelines, Part I, Chapter 3, at Section W ("Minimum Project Application Requirements"), Section AA ("Project Pre-Inspection"), and Section BB ("Project Post-Inspection"); *see also* Proposal TSD at 8–9.

Second, the applicable portions of the 2008 and 2010 Prop 1B guidelines and the 2005, 2008 and 2011 Carl Moyer Program guidelines specifically define the required elements of each contract and the types of actions that constitute violations of such contracts. For example, under the 2008 and 2010 Prop 1B guidelines, each equipment project contract must include: (1) A unique "tracking number"; (2) the equipment owner's contact information; (3) the original application submitted by the equipment owner; (4) requirements for the equipment owner to submit reports to the local agency annually or biennially; (5) the equipment owner's agreement to allow ongoing evaluations and audits of equipment and documentation by the District, CARB, or their designated representative(s); and (6) requirements for the equipment owner to retain all records pertaining to the program (*i.e.,* invoices, contracts, and correspondence) for at least two years after the equipment project ends or three years after final payment, whichever is later. *See* 2008 Prop 1B guidelines at Section III.D.10 ("Equipment project contracts") and 2010 Prop 1B guidelines at Section IV.A.11 ("Equipment project contracts"); *see also* Proposal TSD at 14–15. Additionally, under the same guidelines, the following actions (among others) are specifically identified as contract violations: (1) Failure to meet the terms and conditions of an executed equipment project contract, including equipment operating conditions and geographic restrictions; (2) failure to allow for an electronic monitoring device or tampering with an installed device or data; (3) insufficient, incomplete, or faulty equipment project documentation; and (4) failure to provide required documentation or reports in a timely manner. *See* 2008 Prop 1B guidelines at Section IV.G

(“Equipment Project Non-Performance”) and 2010 Prop 1B guidelines at VI.I (“Equipment Project Non-Performance”); *see also* Proposal TSD at 14–15.

Similarly, under the 2005, 2008 and 2011 Carl Moyer Program Guidelines, each equipment project contract must include: (1) The name and contact information of the grantee; (2) specified timeframes for “project completion” (the date the project post-inspection confirms that the project has become operational) and “project implementation” (the project life used in the project cost-effectiveness calculation); (3) detailed information on both baseline and new vehicles, equipment, and/or engines, including documentation adequate to establish historical annual usage; (4) requirements for the grantee to maintain the vehicle, equipment and/or engine according to the manufacturer’s specifications for the life of the project; (5) annual reporting requirements; (6) a provision authorizing the District, CARB, and their designees to conduct fiscal audits and to inspect the project engine, vehicle, and/or equipment and associated records during the contract term, and (7) requirements to maintain and retain project records for at least two years after contract expiration or three years after final project payment, whichever is later. *See* 2005 Carl Moyer Program Guidelines, Part I, Chapter 2 at Section VIII (“Minimum Contract Requirements”); 2008 Carl Moyer Program Guidelines, Part III, Part III at Section 29 (“Minimum Contract Requirements”); and 2011 Carl Moyer Program Guidelines, Part I, Chapter 3 at Section Z (“Minimum Contract Requirements”). Additionally, the 2011 Carl Moyer Program Guidelines explicitly require that each contract “specify that by executing the contract, the grantee understands and agrees to operate the vehicle, equipment, and/or engine according to the terms of the contract” and describe the potential repercussions to the grantee for non-compliance with contract requirements. *See* 2011 Carl Moyer Program Guidelines, Part I, Chapter 3 at Section Z.11 (“Repercussions for Non-Performance”) and Section FF (“Nonperforming Projects”); *see also* 2005 Carl Moyer Program Guidelines, Part I, Chapter 2 at Section VIII.G (“Repercussions for Nonperformance”); and 2008 Carl Moyer Program Guidelines, Part III, Part III at Section 35 (“Nonperforming Projects”). The 2011 Carl Moyer Program Guidelines also specifically identify types of actions on the part of the District that CARB may treat as violations of program requirements—*e.g.,* misuse of Carl Moyer Program funds and insufficient, incomplete, or inaccurate project documentation. *See* 2011 Carl Moyer Program Guidelines at Section U (“Program Non-Performance”).

Third, the applicable portions of the Prop 1B guidelines and Carl Moyer Program guidelines require that all grantees submit specific types of project records to the District and also require the District to maintain such records for specified periods of time. Specifically, as discussed above, under the 2008 Prop 1B guidelines, the 2010 Prop 1B guidelines, and the 2005, 2008 and 2011 Carl Moyer Program guidelines, each contract executed by the District must require the grantee to maintain project records for at least two years after contract expiration or three years after final project payment, whichever is later, and to submit annual or biennial reports to the District. *See* 2008 Prop 1B guidelines at Section III.D.10 (“Equipment project contracts”), 2010 Prop 1B guidelines at Section IV.A.11 (“Equipment project contracts”), 2005 Carl Moyer Program Guidelines, Part I, Chapter 2 at Section VIII (“Minimum Contract Requirements”); 2008 Carl Moyer Program Guidelines, Part III, Part III at Section 29 (“Minimum Contract Requirements”); and 2011 Carl Moyer Program Guidelines, Part I, Chapter 3 at Section Z (“Minimum Contract Requirements”); *see also* Proposal TSD at 8–9 and 14–15. Additionally, the 2008 Prop 1B guidelines require the District to retain all “program records” (*e.g.,* invoices, contracts, and correspondence) for at least two years after the project ends or three years after final payment, whichever is later. *See* 2008 Prop 1B guidelines, Chapter II, Section D.10.b (“General Program provisions”). The 2010 Prop 1B guidelines require the District to retain “program records” for 35 years after the bond issuance date providing the funds for the grant, or to send all records to CARB by the end date of the grant agreement. *See* 2010 Prop 1B guidelines, Chapter II, Section E.10.b (“General Program provisions”). Under the Carl Moyer Program Guidelines, the District must keep each “project file” for a minimum of two years after the end of the contract term or a minimum of three years after final payment, whichever is later. *See* 2011 Carl Moyer Program Guidelines, Chapter 3, Section V (“ARB Audit of Air Districts”) at 3–25. A “project file” generally includes a copy of the application, a completed pre- and post-inspection form, and the annual reports submitted by the grantee. *See id.* at Section X.6, Section AA.4, Section BB.1.(G), and Section DD.3. These requirements of the Carl Moyer Program and Prop 1B guidelines ensure that grantees submit, and that the District maintains, project documents sufficient for the EPA and the public to verify the emission reductions attributed to these projects in the Emission Reduction Report.

To demonstrate how the public can quantify and verify the emission reductions identified in the Emission Reduction Report, we randomly selected 0.5% of the projects in Appendix H of the Emission Reduction Report and requested that CARB provide to us the information necessary to verify the emission reduction calculations for these projects. From Appendix H.1, which lists the Carl Moyer projects included in the Emission Reduction Report, we randomly selected the projects identified in Table 1.

TABLE 1—SELECTION OF CARL MOYER PROJECTS FROM THE EMISSION REDUCTION REPORT

Project No.	Carl Moyer Guideline year	Source category	Technology	Post inspection date	Project life	2014 NO_X (tpy)	2014 $PM_{2.5}$ (tpy)
G–0014–A	2008	Off-Road Equipment—Construction.	Retrofit	12/28/10	5	0.000	0.018
S–1301	2005	Off-Road Equipment—Mobile Agricultural.	Repower	10/16/09	7	2.610	0.092
				08/17/09	7	4.040	0.120
C–2570	2005	Stationary and Portable Agricultural Engines.	Repower	01/12/10	10	9.880	0.331
				01/12/10	5	7.070	0.129

TABLE 1—SELECTION OF CARL MOYER PROJECTS FROM THE EMISSION REDUCTION REPORT—Continued

Project No.	Carl Moyer Guideline year	Source category	Technology	Post inspection date	Project life	2014 NO_X (tpy)	2014 $PM_{2.5}$ (tpy)
C–14205	2011	Stationary and Portable Agricultural Engines.	Repower	04/25/14	10	1.570	0.055

From Appendix H.2, which lists the Prop 1B Heavy Duty Diesel Truck Replacement projects included in the Emission Reduction Report, we randomly selected the projects identified in Table 2.

TABLE 2—SELECTION OF PROP 1B PROJECTS FROM THE EMISSION REDUCTION REPORT

Equipment project ID	Prop 1B Guideline year	Contract term	Post-inspection date	2014 NO_X (lbs/yr)	2014 $PM_{2.5}$ (lbs/yr)
G08GMCT1_03079	2010	5	01/02/13	10281.31771	229.6259777
G08GMCT1_00642	2010	5	08/21/12	1724.9954	164.035448
G08GMCT1_02930	2010	5	07/25/13	0	0
G07GMCT3_01246	2008	5	06/01/10	8012.6276	235.703448
G07GMCT3_00301	2008	5	09/30/10	394.2153	22.0965876
G07GMCT3_00437	2008	5	01/01/11	3756.22742	110.4951004
G07GMCT3_00377	2008	5	03/04/11	2909.28645	92.691702

We independently calculated the emission reductions for the selected projects using additional project information submitted by CARB at our request and found that the emission reduction calculations for all of the selected projects were replicable, with the exception of one project that was erroneously included in the Emission Reduction Report and accounted for 0 reductions. *See* U.S. EPA Region 9, Memorandum to File dated April 26, 2016, "Sample emission reduction calculations for selected Carl Moyer and Prop 1B projects," Docket No. EPA–R09–OAR–2015–0489 and references therein. Additionally, at our request, CARB submitted the project application, grant agreement and documentation of destruction for one Carl Moyer Program project (Project Number C–2570, Stationary and Portable Agricultural Engines, Repower, 2005 Carl Moyer Guidelines) and one Prop 1B Program project (Equipment Project ID G07GMCT3_01246, Heavy Duty Diesel Truck Replacement, 2008 Prop 1B Guidelines). *See* email dated April 19, 2016, from Sylvia Vanderspek (CARB) to Jeanhee Hong (USEPA Region 9), including attachments. We evaluated the information contained in these project records to verify CARB's emission reduction calculations in the Emission Reduction Report.

For Carl Moyer project C–2570, the project application contains information about the existing and new engine (including engine make, model year, horsepower, and tier), engine function and type (*e.g.,* stationary or portable), the project life, the hours of operation, and percentage of usage in the San Joaquin Valley. *See* San Joaquin Unified Valley Air Pollution Control District (SJVUAPCD), Application C–2570, Heavy-Duty Engine Program Agricultural Pump Engine Component, Diesel Engine to Electric Motor Repower Option ("Carl Moyer Application C–2570") at section 2, section 3 and accompanying table ("For Internal Use Only")).[2] The project agreement, which is the contract between the grantee and the SJVUAPCD, includes a description of the engines, a requirement to destroy the existing engine, the duration of the terms of the agreement, annual reporting requirements, a noncompliance provision for reporting, and provisions concerning District audits. *See* SJVUAPCD, Agreement C–2570, Heavy-Duty Engine Emission Reduction Incentive Program Funding Agreement (Electric Agricultural Pump Motor Repower), July 30, 2009 ("Carl Moyer Agreement C–2570") at section 2, section 3, section 5, section 6, and section 21. Finally, pre- and post-inspection monitoring reports for project C–2570 include photographic evidence of engine information and destruction of the old engine. *See* Heavy-Duty Program Monitoring Report, pre-inspection and post inspection, project number C–2570 ("Carl Moyer Monitoring Reports C–2570"). Consistent with the requirements of the 2005 Carl Moyer Program guidelines at Part I, chapter 2, sections V.D, VIII, and IX, these project records contain all of the information necessary to verify whether project C–2570 was implemented as required and achieved the emission reductions calculated for this project.

Similarly, for Prop 1B project G07GMCT3_01246, the project application contains information about the existing and new engine (including engine make, model year, gross vehicle weight rating (GVWR), Vehicle Identification Number (VIN), and horsepower), the annual vehicle-miles-traveled (VMT) for both the existing and new engine, and percentage of usage in the San Joaquin Valley. *See* SJVUAPCD, Application P–0442,[3] Proposition 1B: Good Movement Emission Reduction Program Component, Truck Replacement ("Prop 1B Application G07GMCT3_01246") at sections 2–4.[4] The project agreement, which is the contract between the grantee and the SJVUAPCD, includes a description of the existing and new engines, a requirement to destroy the existing engine, the duration of the terms of the agreement, annual reporting requirements, nonperformance provisions, and provisions concerning District audits. *See* SJVUAPCD, Agreement P–0442–A, Proposition 1B: Goods Movement Emission Reduction Program Funding Agreement (Truck Replacement), March 16, 2010 (''Prop 1B Agreement G07GMCT3_01246'') at sections 2, 3, 5, 6.F, 7, 12, and 23. Finally, post-inspection monitoring reports for project G07GMCT3_01246 include photographic evidence of engine information and destruction of the old engine. *See* Proposition 1B Program Truck Replacement Option, Exist (Old) Truck Post-Monitoring Inspection, Project Number P–0442–A (''Prop 1B Monitoring Reports G07GMCT3_01246''). Consistent with the requirements of the 2008 Prop 1B Guidelines at sections III.D.10, III.D.14, IV.D and Appendix A, Section F, these project records contain all of the information necessary to verify whether Project G07GMCT3_01246 was implemented as required and achieved the emission reductions calculated for this project.

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[2] Personal information has been redacted from each document for privacy reasons.

[3] These project documents are labeled with the District-only identification number "P–0442." According to CARB, the Goods Movement Online Database (GMOD) includes both the District identifier (P–0442) and the CARB Equipment Project ID (G07GMCT3_01246). *See* email dated May 9, 2016, from Austin Hicks (CARB) to Idalia Pérez (USEPA Region 9), RE: "Prop 1B Application I Numbers" and Memorandum dated May 2, 2016, from Idalia Pérez (USEPA Region 9) to File, RE: "Call with ARB regarding questions on Prop 1B documentation."

[4] Personal information has been redacted from each document for privacy reasons.

Any member of the public can obtain project-related documents maintained by the State and/or District by submitting a request for such documents under the California Public Records Act. *See* Ca. Gov't Code §§ 6250–6276.48. Accordingly, the EPA and citizens can obtain the information necessary to quantify and verify the emission reductions identified in the Emission Reduction Report.

We also disagree with Earthjustice's assertion that there is no way to verify whether the emission reductions attributed to the projects identified in the Emission Reduction Report are ''surplus'' to existing requirements. As an initial matter, we note that both the Carl Moyer Program guidelines and the Prop 1B guidelines generally require that funded projects achieve emission reductions not required by any federal, state or local regulation or other legal mandate. *See* 2005 Carl Moyer Guidelines, Part I, Section VIII.D; 2008 Carl Moyer Guidelines, Part III, Section (27)(i); 2011 Carl Moyer Guidelines, Part 1, Chapter 2; 2008 Prop 1B Guidelines, Section III.B.1 at 47; and 2010 Prop 1B Guidelines, Section III.B.1 at 57.

Earthjustice highlights ''stationary and portable farm engines'' as a source category for which the project life varies from two to ten years and claims that there is no way to know whether or not these projects were counted for only the years in which their emission reductions were surplus. We assume the commenter intended to refer to the ''Stationary and Portable Agricultural Engines'' source category under the Carl Moyer Program. Two of the Carl Moyer projects that we randomly selected for evaluation (identified in Table 1) are within this source category (project numbers C–2570 and C–14205). According to CARB, these two projects were of the equipment type ''Stationary Agricultural Irrigation Pump.'' *See* email dated November 12, 2015, from Sylvia Vanderspek (CARB) to Andrew Steckel (USEPA Region 9). These engines are subject to CARB's Airborne Toxic Control Measure (ATCM) for Stationary Compression Ignition (CI) Engines in title 17, sections 93115—93115.15 of the California Code of Regulations (17 CCR §§ 93115—93115.15) (hereafter ''Stationary Engine ATCM''). Table 7 of the Stationary Engine ATCM provides a summary of requirements for in-use noncertified stationary diesel-fueled engines used in agricultural operations and Table 8 of the Stationary Engine ATCM provides a summary of requirements for certified in-use Tier 1 and Tier 2 engines used in agricultural operations. *See* 17 CCR § 93115.8, Table 7 and Table 8.

The emission reductions attributed to project C–14205 and project C–2570 engine #1 during the January 1–December 31, 2014 timeframe were surplus to the requirements of the Stationary Engine ATCM because they occurred before the earliest ATCM compliance deadline applicable to these engines, which was December 31, 2014. The emission reductions attributed to project C–2570 engine #2 during the January 1–December 31, 2014 timeframe, however, were not entirely surplus because that engine was required to comply with the Stationary Engine ATCM's NO_X and $PM_{2.5}$ emission limits for in-use noncertified stationary diesel-fueled engines used in agricultural operations by December 31, 2010.[5] *See* Table 3.

TABLE 3—STATIONARY ENGINE ATCM COMPLIANCE DEADLINES APPLICABLE TO CARL MOYER PROGRAM PROJECTS C–2570 AND C–14205

Project No.	Equipment identifier	Fuel type	Horsepower	Existing engine certification	Deadline for compliance with stationary engine ATCM[6]	New engine	Project life	Post inspection date
C–2570	1	Diesel	385	Tier 1 Standard	Later of 12/31/14 or 12 years after the date of initial installation.	Electric	10	01/12/10
C–2570	2	Diesel	420	Uncontrolled (uncertified).	12/31/10	Electric	5	01/12/10
C–14205	1	Diesel	335	Tier 3 Standard	N/A	Electric	10	04/25/14

Source: Email dated December 3, 2015 from Austin Hicks (CARB) to Andrew Steckel (USEPA Region 9), RE: ''Additional information request to support final action on ARB Incentive Report,'' including attachments.

Given this information, we have assumed conservatively that all emission reductions attributed to Carl Moyer Program projects in the ''Stationary and Portable Agricultural Engines'' source category in the Emission Reduction Report are not surplus and, therefore, are not creditable for SIP purposes at this time. Stationary and portable agricultural engine projects account for 2.829 tpd of the NO_X emission reductions and 0.066 tpd of the direct $PM_{2.5}$ emission reductions identified in the Emission Reduction Report as shown in Table 4. *See* Emission Reduction Report, Appendix H1 at pp. 8–29.

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[5] Because the existing uncertified engine for project C–2570 engine #2 was replaced with an electric unit, this project did achieve some surplus emission reductions beyond those required by the Stationary Engine ATCM.

[6] *See* 17 CCR § 93115.8, Table 7 and Table 8.

TABLE 4—EMISSION REDUCTIONS FROM CARL MOYER STATIONARY AND PORTABLE AGRICULTURAL ENGINE REPOWER PROJECTS

Carl Moyer guideline year	2014 NO_X (tpd)	2014 $PM_{2.5}$ (tpd)
2005	2.675	0.063
2008	0.132	0.002
2011	0.022	0.001
Total Reductions	2.829	0.066

Source: Emission Reduction Report, Appendix H1 at pp. 27–29.

We are therefore subtracting these amounts from the total amounts of NO_X and direct $PM_{2.5}$ emission reductions identified in the Emission Reduction Report (7.8 tpd of NO_X emission reductions and 0.2 tpd direct $PM_{2.5}$ emission reductions), and crediting the Emission Reduction Report with only 4.971 tpd of NO_X emission reductions and 0.134 tpd of direct $PM_{2.5}$ emission reductions toward the State's 2014 emission reduction commitment in the 2008 $PM_{2.5}$ Plan.

Earthjustice argues that in order to determine whether these projects were counted only for the years during which they could be considered surplus, one would need to know the type of engine that was used as a replacement; the horsepower of the engine used as a replacement; the tier of the original agricultural engine; and fleetwide particulate matter (''PM'') levels. We agree that information about the type of engine that was used as a replacement, the horsepower of the new engine, and the tier of the original agricultural engine is necessary to determine whether the emission reductions attributed to a particular Carl Moyer project are surplus. As explained above, project documents that the District is required to maintain under the Carl Moyer and Prop 1B program guidelines, which CARB submitted to the EPA at our request, identify all of this information. With respect to fleetwide PM levels, we note that this information is not necessary to determine the ATCM compliance date applicable to a stationary agricultural engine, because the requirements of the Stationary Engine ATCM do not vary based on fleetwide PM levels. *See generally* 17 CCR §§ 93115–93115.15. Carl Moyer projects C–2570 and C–14205 are stationary agricultural engines subject to the Stationary Engine ATCM. *See* email dated November 12, 2015, from Sylvia Vanderspek (CARB) to Andrew Steckel (USEPA Region 9). Thus, information about fleetwide PM levels is not necessary to determine whether these projects achieved surplus emission reductions. We agree with Earthjustice that information concerning fleetwide PM levels is necessary to determine certain compliance dates under the ATCM for diesel particulate matter from portable engines. *See* 17 CCR § 93116.3. To the extent the commenter intended to argue that this information is necessary to determine whether a Carl Moyer project for a portable engine will achieve emission reductions that are surplus to existing requirements, we understand that CARB would provide such information upon request under the California Public Records Act and that the public can, therefore, verify whether the emission reductions attributed to any such project are surplus.

Based on these reviews, we find that the Emission Reduction Report contains information adequate to enable the EPA and citizens to obtain emissions-related information necessary to quantify and verify the emission reductions attributed to the identified Carl Moyer Program and Prop 1B projects.

Comment 3: Earthjustice states that incentive programs should not ''be approved into the SIP as a replacement for emission reductions from regulations without fulfilling the four fundamental integrity elements'' and urges the EPA to require that emission reductions be enforceable and quantifiable before approving them into the SIP.

Response 3: This action does not incorporate any portion of the Prop 1B program or Carl Moyer Program, or any related guidelines, into the SIP. To the extent Earthjustice intended to state that the EPA should not approve emission reductions from the projects identified in the Emission Reduction Report for credit toward a SIP commitment unless the applicable incentive programs satisfy the EPA's integrity elements, we agree. As explained in our proposed rule and further in Responses 1 and 2 above, the portions of the Prop 1B program and Carl Moyer Program guidelines that apply to the projects identified in the Emission Reduction Report adequately address the EPA's recommended integrity elements for discretionary EIPs. Based on our review of project-specific documentation submitted by CARB at our request, however, we have found that the emission reductions attributed to one Carl Moyer Program project within the ''Stationary and Portable Agricultural Engines'' category were not entirely surplus to existing requirements and, therefore, are not creditable for SIP purposes at this time, or until properly adjusted to account for existing regulations. As a result, we have conservatively assumed that all of the Stationary and Portable Agricultural Engine Carl Moyer projects identified in the Emission Reduction Report are not SIP-creditable and subtracted the emission reductions attributed to these projects from the total amounts of NO_X and direct $PM_{2.5}$ emission reductions identified in the Emission Reduction Report. *See* Response 2. We find that, with this one exception, the Carl Moyer Program and Prop 1B projects identified in the Emission Reduction Report have achieved the NO_X and $PM_{2.5}$ emission reductions attributed to them in the Emission Reduction Report. We are therefore approving 4.971 tpd of NO_X emission reductions and 0.134 tpd of $PM_{2.5}$ emission reductions for credit toward the State's 2014 emission reduction commitment in the 2008 $PM_{2.5}$ Plan.

III. EPA Action

Under sections 110(k)(3) and 301(a) of the Act, the EPA is finalizing a limited approval and limited disapproval of the Emission Reduction Report and crediting the incentive projects identified therein with 4.971 tpd of NO_X reductions and 0.134 tpd of $PM_{2.5}$ reductions toward the State's 2014 emission reduction commitments in the 2008 $PM_{2.5}$ Plan. We are finalizing a limited approval of the Emission Reduction Report because it largely satisfies the applicable CAA requirements. We are simultaneously finalizing a limited disapproval of the Emission Reduction Report because the demonstration therein concerning the Carl Moyer Stationary and Portable Agricultural Engines source category does not satisfy CAA requirements for SIP credit. Our reasons for disapproving the submitted demonstration on this basis are explained in our responses to comments above.

This limited disapproval does not trigger any sanctions clocks under CAA section 179(a) because the Emission Reduction Report was not submitted to address a requirement of part D, title I of the Act or in response to a finding of substantial inadequacy as described in CAA section 110(k)(5) (*i.e.,* a "SIP Call"). The limited disapproval also does not trigger any obligation on the EPA to promulgate a federal implementation plan (FIP) because the disapproval does not create any deficiency in the SIP that must be corrected.

IV. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www2.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA because this action does not impose additional requirements beyond those imposed by state law.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities beyond those imposed by state law.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action does not impose additional requirements beyond those imposed by state law. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, will result from this action.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175, because the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction, and will not impose substantial direct costs on tribal governments or preempt tribal law. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not impose additional requirements beyond those imposed by state law.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

Section 12(d) of the NTTAA directs the EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. The EPA believes that this action is not subject to the requirements of section 12(d) of the NTTAA because application of those requirements would be inconsistent with the CAA.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Population

The EPA lacks the discretionary authority to address environmental justice in this rulemaking.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

L. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 11, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Particulate matter, Reporting and recordkeeping requirements.

Dated: July 21, 2016.

Alexis Strauss,

Acting Regional Administrator, Region IX.

Part 52, Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraph (c)(477) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(477) The following plan revision was submitted on November 17, 2014 by the Governor's designee.

(i) [Reserved]

(ii) *Additional Material.*

(A) California Air Resources Board.

(*1*) "Report on Reductions Achieved from Incentive-based Emission Reduction Measures in the San Joaquin Valley," adopted on October 24, 2014, including appendices F–H.

[FR Doc. 2016–18903 Filed 8–11–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2013–0464; FRL–9950–49–Region 6]

Approval and Promulgation of Air Quality Implementation Plans; Louisiana; Interstate Transport of Air Pollution for the 2008 Ozone National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is disapproving the portion of a Louisiana State Implementation Plan (SIP) submittal pertaining to interstate transport of air pollution which will significantly contribute to nonattainment or interfere with maintenance of the 2008 ozone National Ambient Air Quality Standards (NAAQS) in other states. Disapproval will establish a 2-year deadline, under Clean Air Act (CAA) Section 110(c), for the EPA to promulgate a Federal Implementation Plan (FIP) for Louisiana to address the CAA interstate transport requirements pertaining to significant contribution to nonattainment and interference with maintenance of the 2008 ozone NAAQS in other states, unless the EPA approves a SIP that meets these requirements. Disapproval does not start a mandatory sanctions clock for Louisiana.

DATES: This rule is effective on September 12, 2016.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R06–OAR–2013–0464. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy. Publicly available docket materials are available either electronically through *http://www.regulations.gov* or in hard copy at EPA Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733.

FOR FURTHER INFORMATION CONTACT: Sherry Fuerst 214–665–6454, *fuerst.sherry@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, "we," "us," and "our" means the EPA.

I. Background

This rulemaking addresses an infrastructure SIP submittal from the State of Louisiana addressing, among other things, the requirements of CAA section 110(a)(2)(D)(i)(I), also known as the good neighbor provision, with respect to the 2008 ozone NAAQS. The background for this action is discussed in detail in our June 7, 2016 proposal (81 FR 36496). In that action we proposed to disapprove the portion of the June 4, 2013 Louisiana SIP submittal pertaining to CAA 110(a)(2)(D)(i)(I) which requires that the State prohibit the interstate transport of air pollution which will significantly contribute to nonattainment or interfere with maintenance of the 2008 ozone NAAQS in other states.

In proposing to disapprove the State's SIP submittal as to the good neighbor provision, we noted two specific deficiencies in the Louisiana submission. First, Louisiana cited the State's approved Clean Air Interstate Rule (CAIR) SIP as support for its conclusion that the State satisfied its section 110(a)(2)(D)(i)(I) obligation with respect to the 2008 ozone NAAQS. However, as explained in our proposal, CAIR was invalidated by the D.C. Circuit in *North Carolina* v. *EPA,* 531 F.3d 896 (2008). Even if Louisiana could rely on its CAIR SIP the modeling and rulemaking conducted for both CAIR, or its successor, the Cross-State Air Pollution Rule (CSAPR), 76 FR 48208 (August 8, 2011) addressed the 1997 ozone NAAQS, not the more stringent 2008 ozone NAAQS at issue in this action. Because the Louisiana submittal addressed by this action concerns the State's interstate transport obligations for a different and more stringent standard (the 2008 ozone NAAQS), we stated it is not sufficient to merely cite to older EPA or state implemented programs as evidence of compliance with the current 2008 ozone NAAQS. Second, the State's submittal lacked any technical analysis evaluating or demonstrating whether emissions in Louisiana impacts air quality in another state. As such, we proposed that the submittal did not provide us with a basis to agree with the State's conclusion that the State already has adequate provisions in the SIP to address CAA section 110(a)(2)(D)(i)(I) requirements for the 2008 ozone NAAQS. We did not receive any comments regarding our proposal.

II. Final Action

EPA is disapproving a portion of a June 4, 2013 SIP submittal from Louisiana pertaining to interstate transport of air pollution which will significantly contribute to nonattainment or interfere with maintenance of the 2008 ozone NAAQS in other states. Disapproval will establish a 2-year deadline, under the CAA Section 110(c), for the EPA to promulgate a FIP for Louisiana to address the CAA interstate transport requirements pertaining to significant contribution to nonattainment and interference with maintenance of the 2008 ozone NAAQS in other states, unless the EPA approves a SIP that meets these requirements. Disapproval does not start a mandatory sanctions clock for Louisiana pursuant to CAA section 179 because this action does not pertain to a part D plan for nonattainment areas required under CAA section 110(a)(2)(I) or a SIP call pursuant to CAA section 110(k)(5).

III. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This final action is not a "significant regulatory action" because it is not categorized as "significant" under section 3(f) of Executive Order 12866 and therefore was not submitted to the Office of Management and Budget for review.

B. Paperwork Reduction Act (PRA)

This final action does not impose an information collection burden under the PRA because it does not contain any information collection activities.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action merely disapprove a SIP submission as not meeting the CAA.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. This action does not apply on any Indian reservation land, any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction, or non-reservation areas of Indian country. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it merely disapproves a SIP submission as not meeting the CAA.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

EPA believes the human health or environmental risk addressed by this action will not have potential disproportionately high and adverse human health or environmental effects on minority, low-income or indigenous populations. This action merely disapproves a SIP submission as not meeting the CAA.

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 11, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, and Ozone.

Dated: July 29, 2016.

Ron Curry,

Regional Administrator, Region 6.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart T—Louisiana

■ 2. Section 52.996 is revised to read as follows:

§ 52.996 Disapprovals.

(a) The portion of the SIP submitted on June 4, 2013 addressing Clean Air Act section 110(a)(2)(D)(i)(I) for the 2008 ozone NAAQS is disapproved.

(b) [Reserved]

[FR Doc. 2016–19148 Filed 8–11–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2014–0704; FRL–9950–54–Region 5]

Wisconsin; Approval/Disapproval of Interstate Transport Requirements for the 2008 Ozone NAAQS

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is partially approving and partially disapproving elements of State Implementation Plan (SIP) submission from Wisconsin regarding the infrastructure requirements of section 110 of the Clean Air Act (CAA) for the 2008 ozone National Ambient Air Quality Standards (NAAQS). The infrastructure requirements are designed to ensure that the structural components of each state's air quality management program are adequate to meet the state's responsibilities under the CAA. This action pertains specifically to infrastructure requirements concerning interstate transport provisions for which Wisconsin made a SIP submission that, among other things, certified that the existing SIP was sufficient to meet the interstate transport requirements for the 2008 ozone NAAQS.

DATES: This final rule is effective on September 12, 2016.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R05–OAR–2014–0704. All documents in the docket are listed on the *www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *i.e.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either through *www.regulations.gov* or please contact the person identified in the "For Further Information Contact" section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Sarah Arra, Environmental Scientist, Attainment Planning and Maintenance Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–9401, *arra.sarah@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever "we," "us," or "our" is used, we mean EPA. This supplementary information section is arranged as follows:

I. What is the background of this SIP submission?
II. What action did EPA propose on the SIP submission?
III. What is our response to comments received on the proposed rulemaking?
IV. What action is EPA taking?
V. Statutory and Executive Order Reviews.

I. What is the background of this SIP submission?

This rulemaking addresses CAA section 110(a)(2)(D)(i) requirements in an infrastructure SIP submission addressing the applicable infrastructure requirements with respect to the 2008 ozone NAAQS, submitted by the Wisconsin Department of Natural Resources (WDNR) on June 20, 2013, and clarified in a letter dated January 28, 2015.

The requirement for states to make a SIP submission of this type arises out of CAA section 110(a)(1). Pursuant to section 110(a)(1), states must make SIP submissions "within 3 years (or such shorter period as the Administrator may prescribe) after the promulgation of a national primary ambient air quality standard (or any revision thereof)," and these SIP submissions are to provide for the "implementation, maintenance, and enforcement" of such NAAQS. The statute directly imposes on states the duty to make these SIP submissions, and the requirement to make the submissions is not conditioned upon EPA's taking any action other than promulgating a new or revised NAAQS.

Section 110(a)(2) includes a list of specific elements that "[e]ach such plan" submission must address. EPA commonly refers to such state plans as "infrastructure SIPs."

This rulemaking takes action on two CAA section 110(a)(2)(D)(i) requirements which apply to these submissions. In particular, section 110(a)(2)(D)(i)(I) requires SIPs to include provisions prohibiting any source or other type of emissions activity in one state from contributing significantly to nonattainment of the NAAQS ("prong one"), or interfering with maintenance of the NAAQS ("prong two"), by any another state. Section 110(a)(2)(D)(i)(II) requires that infrastructure SIPs include provisions prohibiting any source or other type of emissions activity in one state from interfering with measures required to prevent significant deterioration (PSD) of air quality ("prong three") and to protect visibility ("prong four") in another state. This rulemaking addresses prongs one and two of this CAA section. The majority of the other infrastructure elements were approved in rulemakings on September 11, 2015 (80 FR 54725).

II. What action did EPA propose on the SIP submission?

The proposed rulemaking associated with today's final action was published on March 16, 2016 (81 FR 14025). In that action, EPA proposed to disapprove the Wisconsin SIP for the prong two requirement because the WDNR SIP submission did not provide an adequate technical analysis demonstrating that the state's SIP contained adequate provisions prohibiting emissions that will significantly contribute to nonattainment or interfere with the 2008 ozone NAAQS in any other state and because EPA's most recent modeling indicated that emissions from Wisconsin were projected to contribute to projected downwind maintenance receptors in another state. EPA also proposed to approve the Wisconsin SIP for the prong one requirement because, although WDNR did not provide information or analyses explaining why existing SIP provisions are adequate to prevent significant contribution to nonattainment in downwind states, EPA's independent modeling presented in the Notice of Data Availability and the Cross-State Air Pollution Update Rule indicated that Wisconsin emissions were not linked to any projected downwind nonattainment receptors. Therefore, EPA proposed to find that the Wisconsin SIP had adequate provisions to prevent such significant contribution to nonattainment for the 2008 ozone standard.

III. What is our response to comments received on the proposed rulemaking?

During the comment period, which ended on April 15, 2016, EPA did not receive any comments on the Wisconsin portion of the proposed notice. Comments pertaining to Ohio and Indiana are addressed in a June 15, 2016 rulemaking (81 FR 38957).

IV. What action is EPA taking?

EPA, as proposed, is approving prong one and disapproving prong two of a required infrastructure element with respect to CAA section 110(a)(2)(D)(i), interstate transport, for the 2008 ozone NAAQS. The approval is based on the June 20, 2013 SIP submission in which Wisconsin certified that the current SIP is sufficient to meet the CAA requirements. The disapproval portion of this action triggers an obligation under CAA section 110(c) for EPA to promulgate a Federal Implementation Plan (FIP) no later than two years from the effective date of this disapproval, if EPA has not approved a SIP revision or revisions addressing the deficiencies identified in this action. The disapproval in this action is not tied to attainment planning requirements and therefore does not start any sanction clocks.

V. Statutory and Executive Order Reviews.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

B. Paperwork Reduction Act (PRA)

This rule does not impose an information collection burden under the provisions of the PRA.

C. Regulatory Flexibility Act (RFA)

The Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden or otherwise has a positive economic effect on the small entities subject to the rule. This action merely proposes to disapprove state law as not meeting Federal requirements and imposes no additional requirements beyond those imposed by state law.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. It will not have substantial direct effects on tribal governments. Thus, Executive Order 13175 does not apply to this rule.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children because it proposes to disapprove a state rule.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

EPA believes the human health or environmental risk addressed by this action will not have potential disproportionately high and adverse human health or environmental effects on minority, low-income or indigenous populations.

Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 11, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone.

Dated: August 1, 2016.

Robert A. Kaplan,

Acting Regional Administrator, Region 5.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

■ 2. Section 52.2591 is amended by revising paragraph (g) to read as follows:

§ 52.2591 Section 110(a)(2) infrastructure requirements.

* * * * *

(g) Approval—In a June 20, 2013, submission with a January 28, 2015, clarification, Wisconsin certified that the state has satisfied the infrastructure SIP requirements of section 110(a)(2)(A) through (H), and (J) through (M) for the 2008 ozone NAAQS. For 110(a)(2)(D)(i)(I), we are approving prong one and disapproving prong two. We are not taking action on the prevention of significant deterioration requirements related to section 110(a)(2)(C), (D)(i)(II), and (J) and the state board requirements of (E)(ii). We will address these requirements in a separate action.

* * * * *

[FR Doc. 2016–19025 Filed 8–11–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–2000–0006; FRL–9950–62–Region 2]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Deletion of the Jackson Steel Superfund Site

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Jackson Steel Superfund site (Site), located in the Village of Mineola, Nassau County, New York, contains a building formerly used as a metal-forming facility. The Site is bordered to the north by commercial spaces and single-family dwellings, to the east by a two-story apartment complex, to the south by a daycare center and to the west by an office building and restaurant.

The Environmental Protection Agency (EPA) Region 2 is publishing this direct final Notice of Deletion (NOD) of the Site from the National Priorities List (NPL). The NPL, promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). This direct final deletion is being published by EPA with the concurrence of the State of New York, through the New York State Department of Environmental Conservation (NYSDEC), because EPA has determined that all appropriate response actions under CERCLA have been completed at the Site and that the soil on the Site and the groundwater beneath the Site no longer pose a threat to public health or the environment. Because elevated concentrations of volatile organic compounds (VOCs) are present under the slab of the vacant Jackson Steel building and the occupied daycare center, operation and maintenance of the subslab vapor intrusion mitigation systems under the daycare center, periodic vapor intrusion monitoring, and five-year reviews will continue. The deletion does not preclude future actions under Superfund.

DATES: This direct final deletion will be effective September 26, 2016 unless EPA receives adverse comments by September 12, 2016. If adverse comments are received, EPA will publish a timely withdrawal of this direct final NOD in the **Federal**

Register, informing the public that the deletion will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID no. EPA–HQ–SFUND–2000–0006, by one of the following methods:

- *Web site: http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Email: singerman.joel@epa.gov.*
- *Fax:* To the attention of Joel Singerman at 212–637–3966.
- *Mail:* To the attention of Joel Singerman, Chief, Central New York Remediation Section, Emergency and Remedial Response Division, U.S. Environmental Protection Agency, Region 2, 290 Broadway, 20th Floor, New York, NY 10007–1866.
- *Hand Delivery:* Superfund Records Center, 290 Broadway, 18th Floor, New York, NY 10007–1866 (telephone: 212–637–4308). Such deliveries are only accepted during the Record Center's normal hours of operation (Monday to Friday from 9:00 a.m. to 5:00 p.m.). Special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID no. EPA–HQ–SFUND–2000–0006. EPA's policy is that all comments received will be included in the Docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be confidential business information (CBI) or other information for which disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or via email. The *http://www.regulations.gov* Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comments. If you send comments to EPA via email, your email address will be included as part of the comment that is placed in the Docket and made available on the Web site. If you submit electronic comments, EPA recommends that you include your name and other contact information in the body of your comments and with any disks or CD–ROMs that you submit. If EPA cannot read your comments because of technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comments fully. Electronic files should avoid the use of special characters and any form of encryption and should be free of any defects or viruses.

Docket: All documents in the Docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information for which disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly-available Docket materials can be obtained either electronically at *http://www.regulations.gov* or in hard copy at:

U.S. Environmental Protection Agency, Region 2, Superfund Records Center, 290 Broadway, 18th Floor, New York, NY 10007–1866. *Phone:* 212–637–4308. *Hours:* Monday to Friday: 9:00 a.m. to 5:00 p.m.

Town of North Hempstead, 200 Plandome Road, Manhasset, NY 11030. *Phone:* (516) 489–5000. *Hours:* Monday–Friday, 8:15 a.m.–4:00 p.m.

Garden City Public Library, 60 Seventh Street, Garden City, NY 11530. *Phone:* (516) 742–8405. *Hours:* Monday–Thursday: 9:30 a.m.–9:00 p.m.; Friday and Saturday: 9:30 a.m.–5:00 p.m.; Sat: 9:30 a.m.–5:00 p.m. and Sunday: 1:00 p.m.–5:00 p.m.

Village of Mineola Hall, 155 Washington Avenue, Mineola, NY 11501. *Phone:* (516) 746–0750. *Hours:* Monday–Friday 8:30 a.m.–4:30 p.m.

FOR FURTHER INFORMATION CONTACT: Joel Singerman, Chief, Central New York Remediation Section, by mail at Emergency and Remedial Response Division, U.S. Environmental Protection Agency, Region 2, 290 Broadway, 20th Floor, New York, NY 10007–1866; telephone at 212–637–4258; fax at 212–637–3966; or email at *singerman.joel@epa.gov.*

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. NPL Deletion Criteria
III. Deletion Procedures
IV. Basis for Site Deletion
V. Deletion Action

I. Introduction

EPA Region 2 is publishing this direct final NOD of the Site from the NPL. The NPL constitutes Appendix B of 40 CFR part 300, which is the NCP, which EPA promulgated pursuant to Section 105 of CERCLA, as amended. EPA maintains the NPL as the list of releases that appear to present a significant risk to public health, welfare, or the environment. The releases on the NPL may be the subject of remedial actions financed by the Hazardous Substance Superfund (Fund). As described in Section 300.425(e)(3) of the NCP, a site deleted from the NPL remains eligible for Fund-financed remedial action if future conditions at the site warrant such actions.

Section II of this document explains the criteria for deleting sites from the NPL. Section III discusses procedures that EPA is using for this action. Section IV discusses the Site and demonstrates how it meets the deletion criteria. Section V discusses EPA's action to delete the Site from the NPL unless adverse comments are received during the public comment period.

II. NPL Deletion Criteria

The NCP establishes the criteria that EPA uses to delete sites from the NPL. In accordance with 40 CFR 300.425(e), sites may be deleted from the NPL where no further response is appropriate. In making such a determination pursuant to 40 CFR 300.425(e), EPA will consider, in consultation with the State, whether any of the following criteria have been met:

i. Responsible parties or other parties have implemented all appropriate response actions required;

ii. all appropriate Fund-financed responses under CERCLA have been implemented, and no further action by responsible parties is appropriate; or

iii. the remedial investigation (RI) has shown that the release of hazardous substances poses no significant threat to public health or the environment and, therefore, taking of remedial measures is not appropriate.

Pursuant to CERCLA Section 121(c) and the NCP, EPA conducts five-year reviews to ensure the continued protectiveness of remedial actions where hazardous substances, pollutants, or contaminants remain at a site above levels that allow for unlimited use and unrestricted exposure. EPA conducts such five-year reviews even if a site is deleted from the NPL. EPA may initiate further action to ensure continued protectiveness at a deleted site if new information becomes available that indicates it is appropriate. Whenever there is a significant release from a site deleted from the NPL, the deleted site may be restored to the NPL without application of the hazard ranking system.

III. Deletion Procedures

The following procedures apply to the deletion of the Site:

(1) EPA consulted with the State of New York prior to developing this direct final NOD and the NOID also published today in the "Proposed Rules" section of the **Federal Register**.

(2) EPA has provided the State with 30 working days for review of this notice and the parallel NOID prior to their publication today, and the State,

through NYSDEC, has concurred on the deletion of the Site from the NPL.

(3) Concurrent with the publication of this direct final NOD, a notice of the availability of the parallel NOID is being published in a major local newspaper, the *Mineola American*. The newspaper notice announces the 30-day public comment period concerning the NOID of the Site from the NPL.

(4) EPA placed copies of documents supporting the proposed deletion in the Deletion Docket and made these items available for public inspection and copying at the Site information repositories identified above.

(5) If adverse comments are received within the 30-day public comment period on this deletion action, EPA will publish a timely notice of withdrawal of this direct final NOD before its effective date and will prepare a response to comments. If appropriate, EPA may continue with the deletion process based on the NOID and the comments already received.

The NPL is designed primarily for informational purposes and to assist EPA's management of sites. Section 300.425(e)(3) of the NCP states that the deletion of a site from the NPL does not preclude eligibility for further response actions should future conditions warrant such actions.

IV. Basis for Site Deletion

The following information provides the Agency's rationale for deleting the Site from the NPL.

Site Background and History

The 1.5-acre Site (CERCLIS ID NYD001344456) contains a one-story, 43,000-square-foot building formerly used as a metal-forming facility and an approximately 10,000-square foot paved parking area. It is bordered to the north by commercial spaces and single-family dwellings, to the east by a two-story apartment complex, to the south by a daycare center, and to the west by an office building and restaurant.

The property was used from the mid-1970s until 1991 as a "roll form metal shapes" manufacturing facility. Degreasers, including tetrachloroethylene (PCE), trichloroethylene, and 1,1,1-trichloroethane, were used at the facility until 1985. Sludges from degreasing equipment were stored in drums and in an on-property 275-gallon tank.

The analytical results from samples collected by the Nassau County Department of Health (NCHD) in the early 1990s from within, around, and below three on-property dry wells indicated the presence of VOCs at depths down to 40 feet below the ground surface. VOCs were also detected in groundwater samples collected from monitoring wells located downgradient of the dry wells.

Dumping of wastes into the dry wells and spills and leaks from drums storing various chemicals during the facility's operations are the likely sources of the contamination that was found at the Site.

The Site was proposed for listing on the NPL on October 22, 1999 (40 CFR part 300 [FRL–6462–2]). The Site was listed on the NPL on February 4, 2000 (40 CFR part 300 [FRL–6532–7]).

Following the commencement of RI-related field work in October 2001, because of concerns about the proximity of the Site to the daycare center, NCHD performed air sampling inside the daycare center building. The air samples detected PCE at levels below the New York State Department of Health's (NYSDOH's) guideline for indoor PCE exposure. Given the sensitivity of the population exposed (preschool children), NCHD collected additional samples in December 2001. At that time, indoor testing was also conducted inside the Jackson Steel building and the restaurant located adjacent to the Site. The results indicated that PCE levels in the indoor air of several rooms in the daycare center were above NYSDOH's guideline for PCE. As a result, in January 2002, a subslab depressurization system (*i.e.*, vapor intrusion mitigation system) was installed by EPA. In addition, a ventilation system was installed by the daycare center's contractor. Samples collected to assess the effectiveness of the implemented measures showed that the PCE levels in the air were significantly below NYSDOH's guideline and below EPA's acceptable noncancer risk levels. Because elevated PCE levels were also detected in a billiards club that shared common walls with the Site building and the daycare center, EPA installed a vapor intrusion mitigation system under the concrete slab of this building, as well. The billiards club was subsequently occupied as a retail store, and recently the daycare center (the Learn and Play Daycare Center) expanded to occupy this space, as well. The vapor intrusion mitigation systems were replaced by the property owner's contractor in May 2016.

The results of the RI, which was completed in 2002, indicated that VOCs, semi-volatile organic compounds, pesticides, and metals contamination were present in the surface soil, and VOC contamination was present at several subsurface soil locations. In addition, contamination was found in a trench and sumps located inside the building and dry wells located under the parking lot at the Site.

Groundwater from the three hydrogeologic units underlying the site—the Upper Glacial Aquifer (upper aquifer), Magothy Confining Bed (a low permeability, clay layer separating the upper and deep aquifers), and the Magothy Aquifer (deep aquifer)—were also sampled. VOC contamination above state and federal standards was detected both in the Upper Glacial Aquifer and Magothy Aquifer.

Based upon the results of the RI and a feasibility study, in September 2004, EPA selected a remedy for the Site in a Record of Decision (ROD). The ROD outlined the following remedial action objectives (RAOs):

- Minimize or eliminate contaminant migration from contaminated soils and dry wells to the groundwater;
- minimize or eliminate any contaminant migration from contaminated soils and groundwater to indoor air;
- restore groundwater to levels which meet state and federal standards within a reasonable time frame;
- mitigate the migration of the affected groundwater; and
- reduce or eliminate any direct contact, ingestion, or inhalation threat associated with contaminated soils, soil vapor, contaminated surfaces in the on-property building, and groundwater.

The selected remedy includes the following actions:

- Decontamination of the Jackson Steel building floor;
- in-situ soil vapor extraction (ISVE) to treat the contaminated subsurface soil;
- excavation and off-Site disposal of the contaminated surface soil and contaminated material in on-Site sumps, a trench, and dry wells;
- in-situ chemical oxidation (ISCO) to treat the contaminated groundwater in the Upper Glacial Aquifer;
- extraction and treatment of the contaminated groundwater in the deep aquifer if confirmatory groundwater sampling indicates that the Site is a principal source of the groundwater contamination to the aquifer underlying the Site;
- if it is determined that the Site is a principal source of the groundwater contamination to the deep aquifer underlying the Site, the selected remedy would be expanded, as necessary, to include off-property groundwater contamination; and
- long-term groundwater monitoring.

The soil cleanup objectives were established pursuant to New York State Technical and Administrative Guidance

Memorandum (TAGM) No. 94–HWR–4046 objectives (Division Technical and Administrative Guidance Memorandum: Determination of Soil Cleanup Objectives and Cleanup Levels, Division of Hazardous Waste Remediation, January 24, 1994). As dictated by the TAGM objectives, the soil cleanup levels selected in the ROD were the more stringent cleanup level between a human-health protection value and a value based on protection of groundwater. The groundwater cleanup goals were the more stringent of the state or federal promulgated standards. EPA and New York State Department of Health promulgated health-based, protective Maximum Contaminant Levels (MCLs) that are enforceable standards for various drinking water contaminants. MCLs ensure that drinking water does not pose either a short- or long-term health risk.

The building decontamination and the excavation of the contaminated surface soil and the contaminated material in the building sumps and trench and in the dry wells and their disposal were performed from 2005 to 2006. A total of 170 cubic yards of material was excavated and disposed of at an EPA-approved off-Site facility.

Groundwater ISCO injections were performed between July and December 2005. Approximately, 15,000 gallons of iron-catalyzed sodium persulfate (with small amounts of buffering agents) and 600 gallons of hydrogen peroxide were injected into the aquifer through a network of 20 injection wells to treat the contamination in the Upper Glacial Aquifer.

After a successful pilot test, an ISVE system consisting of nine ISVE wells and 11 vapor monitoring probes began operating in 2005.

A supplemental groundwater investigation was conducted from 2005 to 2006 to determine the source of the Magothy Aquifer contamination underneath the Site and to establish whether there was a relationship between the contamination at the Site and the VOC contamination detected in nearby Village of Mineola Supply Well #4. Based on the results of the investigation, it was concluded that the Site was not a current source of contamination in the Magothy Aquifer. Therefore, EPA decided not to implement the Magothy Aquifer groundwater remedy. An Explanation of Significant Differences (ESD) was issued in 2007, documenting this decision.

While the cleanup objectives for the Upper Glacial Aquifer and soil were met in 2006 and 2008, respectively, EPA continued to operate the ISVE system until 2013 because VOC vapors were still being recovered from underneath the Jackson Steel building. The operation of the ISVE system was discontinued when the levels of vapor removal became too low for the system to continue to be efficient.

The aboveground ISVE infrastructure was removed by EPA in June 2013. From March to April 19, 2016, the groundwater monitoring wells, ISVE wells, vapor monitoring wells, ISCO injection wells, and ISCO monitoring wells, were decommissioned.

Although EPA successfully remediated the soil and the groundwater aquifer immediately underlying the Site, residual levels of VOCs remain. VOCs, even at low levels, can migrate as vapors through the soil into buildings. This process, which is called vapor intrusion, can result in unacceptable human exposures to VOCs inside occupied buildings. This pathway is currently incomplete at the Site, because the building on the site is currently unoccupied, and subslab vapor intrusion mitigation systems prevent the migration of vapors into an adjacent occupied building.

Because the residual levels of VOCs are expected to dissipate slowly, EPA concluded that preventing human exposure to VOCs at the occupied building will be needed for a number of years to ensure the protectiveness of the remedy. Therefore, the existing vapor intrusion mitigation systems will need to continue to operate, and additional actions, from monitoring to the installation of an additional vapor mitigation system, may be needed should the currently unoccupied building be occupied or replaced with another structure in the future. EPA determined that institutional controls (ICs) (*i.e.*, property use restrictions) requiring the continued operation of the subslab vapor intrusion mitigation systems were needed. In addition, EPA determined that ICs requiring vapor intrusion sampling and/or mitigative measures were needed should the unoccupied Jackson Steel building be occupied or replaced with another structure in the future.

EPA issued an ESD on June 20, 2016, documenting its determination to incorporate into the remedy ICs to prevent exposure through vapor intrusion. The ICs will remain in place until the residual VOCs fully dissipate in the subsurface. EPA noted in the ESD that a Vapor Intrusion Management Plan (VIMP) and Institutional Control Implementation and Assurance Plan (ICIAP) would be prepared to ensure that the ICs were appropriately implemented and maintained. In addition, in the ESD EPA noted that it would communicate directly with the Village of Mineola Superintendent of Buildings, requesting that EPA and NYSDEC be notified if the existing building is to be refurbished and used for human occupancy or demolished and a new structure constructed. The correspondence would also request that the Village not issue a Certificate of Occupancy until necessary vapor intrusion-related actions identified by EPA and NYSDEC are carried out.

A VIMP and ICIAP were completed on June 20, 2016.

On June 20, 2016, EPA sent a letter to the Village of Mineola Superintendent of Buildings, requesting that EPA and NYSDEC be notified if the existing building is to be refurbished and used for human occupancy or demolished and a new structure constructed and requested that the Village not issue a Certificate of Occupancy until necessary vapor intrusion-related actions identified by EPA and NYSDEC are carried out. Periodic reminders will be issued to the Village to help ensure the effectiveness of this measure.

On July 27, 2016, notices were placed on the deed of the two parcels occupied by the daycare center and the parcel occupied by the Jackson Steel building. The notice on the deed of the daycare center requires that the subslab vapor intrusion mitigation systems be operated as long as elevated levels of vapors remain under the buildings on the property and the buildings are occupied. The notice on the deed of the Jackson Steel building alerts any potential purchaser, lessee, or other user of the property that EPA and NYSDEC must be notified if and when a determination is made that the existing building will be refurbished and used for human occupancy or demolished and a new structure constructed. EPA intends to effect an environmental easement on the Jackson Steel property in the future once a new owner takes control of the property.

Five-Year Review

It is the policy of EPA to conduct five-year reviews when remedial activities, including monitoring, will continue for more than five years. A five-year review that is required by policy is triggered by the date of the approval of the Preliminary Close-Out Report, which documents that EPA has determined that construction at a site has been completed. For this Site, the Preliminary Close-Out Report was approved on August 30, 2007.

The first five-year review was completed in August 2012. The review concluded that the remedy was functioning as intended in the decision documents and was protecting human health and the environment.

Subsequent to the 2012 five-year review, EPA determined that ICs were necessary to ensure the protectiveness of the remedy, as discussed above. Five-year reviews will be conducted as long as residual VOC levels remain that perpetuate the vapor intrusion concerns described in this ESD. The next five-year review will be conducted by August 2017.

Community Involvement

Public participation activities for the Site have been satisfied as required pursuant to CERCLA Sections 113(k) and 117, 42 U.S.C. 9613(k) and 9617. As part of the remedy selection process, the public was invited to comment on the proposed remedy. All other documents and information that EPA relied on or considered in recommending this deletion are available for the public to review at the information repositories identified above.

Determination That the Site Meets the Criteria for Deletion From the NCP

All of the cleanup requirements for the Site have been met, as described in the September 2006 groundwater Interim Groundwater Remedial Action Report, September 2008 soil Remedial Action Report, August 2007 Preliminary Close-Out Report, July 2016 Final Close-Out Report, and 2012 Five-Year Review report. The State of New York, in a July 29, 2016 letter, concurred with the proposed deletion of the Site from the NPL.

The NCP specifies that EPA may delete a site from the NPL if "all appropriate Fund-financed response under CERCLA has been implemented, and no further response action by responsible parties is appropriate." 40 CFR 300.425(e)(1)(ii). EPA, with the concurrence of the State of New York, through NYSDEC, believes that this criterion for the deletion of the Site has been met in that that the soil on the Site and the groundwater beneath the Site no longer pose a threat to public health or the environment. Consequently, EPA is deleting the Site from the NPL. Documents supporting this action are available in the deletion docket at *http://www.regulations.gov* and at the Site information repositories.

V. Deletion Action

EPA, with the concurrence of the State of New York through NYSDEC, has determined that other than the ongoing operation and maintenance of the vapor intrusion mitigation systems at the daycare center, periodic vapor intrusion monitoring, insuring that the ICs are in place and effective, and five-year reviews, all appropriate responses under CERCLA have been completed at the Site. The soil and groundwater immediately underlying the Site no longer pose a threat to public health or the environment. Therefore, EPA is deleting the Site from the NPL. Periodic vapor intrusion monitoring and five-year reviews will still be required for the Site. The deletion does not preclude future action under CERCLA. Because EPA considers this action to be noncontroversial and routine, EPA is taking this action without prior publication. This action will be effective September 26, 2016 unless EPA receives adverse comments by September 12, 2016. If adverse comments are received within the 30-day public comment period of this action, EPA will publish a timely withdrawal of this direct final NOD before the effective date of the deletion and the deletion will not take effect. EPA will prepare a response to comments and continue with the deletion process on the basis of the NOID and the comments received. In such a case, there will be no additional opportunity to comment.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous waste, Hazardous substances, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: August 2, 2016.

Judith A. Enck,

Regional Administrator, EPA, Region 2.

For the reasons set out in this document, 40 CFR part 300 is amended as follows:

PART 300—NATIONAL OIL AND HAZARDOUS SUBSTANCES POLLUTION CONTINGENCY PLAN

■ 1. The authority citation for part 300 continues to read as follows:

Authority: 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601–9675; E.O. 12777, 56 FR 54757, 3 CFR 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR 1987 Comp., p. 193.

■ 2. Table 1 of Appendix B to part 300 is amended by removing "Jackson Steel," "Mineola/North Hempstead," "NY."

[FR Doc. 2016–19130 Filed 8–11–16; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R8–ES–2015–0170; FFXES11130000–156–FF08E00000]

RIN 1018–BA71

Endangered and Threatened Wildlife and Plants; Removing the San Miguel Island Fox, Santa Rosa Island Fox, and Santa Cruz Island Fox From the Federal List of Endangered and Threatened Wildlife, and Reclassifying the Santa Catalina Island Fox From Endangered to Threatened

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), are removing the San Miguel Island fox (*Urocyon littoralis littoralis*), Santa Rosa Island fox (*U. l. santarosae*), and Santa Cruz Island fox (*U. l. santacruzae*) from the Federal List of Endangered and Threatened Wildlife and are reclassifying the Santa Catalina Island fox (*U. l. catalinae*) from an endangered species to a threatened species. This action is based on a thorough review of the best available scientific and commercial information, which indicates that the threats to the San Miguel Island fox, Santa Rosa Island fox, and Santa Cruz Island fox have been eliminated or reduced to the point that each of the subspecies no longer meets the definition of an endangered species or a threatened species under the Endangered Species Act of 1973, as amended (Act), and that the threats to the Santa Catalina Island fox have been reduced to the point that the subspecies can be reclassified as a threatened species. We also announce the availability of a final post-delisting monitoring plan for the San Miguel Island fox, Santa Rosa Island fox, and Santa Cruz Island fox.

DATES: This rule is effective September 12, 2016.

ADDRESSES: This final rule is available on the Internet at *http://www.regulations.gov* and at the Ventura Fish and Wildlife Office's Web site at *http://www.fws.gov/Ventura/*. Comments, materials, and supporting documentation considered in this rulemaking are available on the Internet at *http://www.regulations.gov* at Docket No. FWS–R8–ES–2015–0170, and are available for public inspection by appointment, during normal business hours at: U.S. Fish and Wildlife Service, Ventura Fish and Wildlife Office, 2493 Portola Road, Suite B, Ventura, CA 93003; by telephone 805–644–1766; or by facsimile 805–644–3958. The post-delisting monitoring plan for the San Miguel Island fox, Santa Rosa Island fox, and Santa Cruz Island fox is available on our Endangered Species Program's national Web site (*http://endangered.fws.gov*) and on the Internet at *http://www.regulations.gov* at Docket No. FWS–R8–ES–2015–0170.

FOR FURTHER INFORMATION CONTACT: Stephen P. Henry, Field Supervisor, U.S. Fish and Wildlife Service, Ventura Fish and Wildlife Office, 2493 Portola Road, Suite B, Ventura, CA 93003; telephone 805–644–1766; facsimile 805–644–3958. If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Previous Federal Actions

On December 10, 2001, we published a proposal to list four subspecies of island foxes as endangered species (66 FR 63654). Please refer to this proposed rule for information on Federal actions prior to December 10, 2001. On March 5, 2004, we published a final rule listing the four subspecies of island foxes as endangered species (69 FR 10335). Please refer to the final Recovery Plan for Four Subspecies of Island Fox (*Urocyon littoralis*) (Service 2015, entire) for a detailed description of Federal actions concerning this species. We did not designate critical habitat for the four subspecies of island fox, as explained in our November 9, 2005, final critical habitat determination (70 FR 67924).

We published a notice announcing the initiation of a review of the status of the San Miguel Island fox, Santa Rosa Island fox, Santa Cruz Island fox, and Santa Catalina Island fox under section 4(c)(2) of the Act (16 U.S.C. 1531 *et seq.*) on March 9, 2015 (80 FR 12521), with the notice announcing the availability of the final recovery plan. On February 16, 2016, we published in the **Federal Register** a status review and proposed rule (81 FR 7723) to remove the San Miguel Island fox, Santa Rosa Island fox, and the Santa Cruz Island fox from the Federal List of Endangered and Threatened Wildlife, and to reclassify the Santa Catalina Island fox from an endangered species to a threatened species.

Background

Please refer to the final Recovery Plan for Four Subspecies of Island Fox (*Urocyon littoralis*) (Service 2015, entire) for a summary of background information on island fox taxonomy, life history, and distribution. We prepared the Recovery Plan by working with a Recovery Team that included public agency representatives, landowners, conservancies, zoological institutions, nonprofits, and academics. The Recovery Plan includes discussion of the following: species description and taxonomy, habitat use, social organization, reproduction, distribution and abundance, threats to the subspecies, and recovery strategies.

Range of the Species

The island fox (*Urocyon littoralis*), a diminutive relative of the gray fox (*U. cinereoargenteus*), is endemic to the California Channel Islands. Island foxes inhabit the six largest of the eight Channel Islands (San Miguel Island, Santa Rosa Island, Santa Cruz Island, Santa Catalina Island, San Nicolas Island, and San Clemente Island) and are recognized as distinct subspecies on each of the six islands. Both morphologic and genetic distinctions support the classification of separate subspecies of island foxes for each island (Collins 1993, entire; Gilbert *et al.* 1990, entire; Goldstein *et al.* 1999, entire; Wayne *et al.* 1991a, entire). We recognize the range of each subspecies to be the island that it inhabits. Islands inhabited by island foxes are owned by four major landowners: the National Park Service (NPS), the U.S. Navy, The Nature Conservancy (TNC), and the Santa Catalina Island Conservancy (CIC), all of whom have management authority for wildlife on their lands. NPS and TNC manage San Miguel Island, Santa Rosa Island, and Santa Cruz Island; in this rule, we reference these three islands as the northern Channel Islands CIC manages the majority of fox habitat on Santa Catalina Island, except the City of Avalon. Santa Catalina Island is the only island with a permanent human population. Human use of the three northern Channel Islands is restricted to visitors and NPS and TNC staff.

Summary of Changes From the Proposed Rule

We did not make substantive changes in this final rule based on the comments that we received during the public comment period, but we added text to clarify some information presented in the proposed rule, added new information to the climate change analysis, and revised population data to reflect information updated since the publication of the proposed rule. For example, peer reviewers recommended we include information about genetic variability present in the current island fox populations and new information about climate change. This information and other clarifications are incorporated into the final rule where appropriate, including in the Summary of Comments and Recommendations, below.

Recovery and Recovery Plan Implementation

Section 4(f) of the Act directs us to develop and implement recovery plans for the conservation and survival of endangered and threatened species unless we determine that such a plan will not promote the conservation of the species. We published a notice announcing the availability of the final recovery plan for the San Miguel Island fox, Santa Rosa Island fox, Santa Cruz Island fox, and Santa Catalina Island fox on March 9, 2015 (80 FR 12521).

The recovery plan (Service 2015, pp. 47–53) includes the recovery goals, recovery objectives, and recovery criteria that we outline below to reclassify the island fox subspecies from endangered species to threatened species and to remove island fox subspecies from the List of Endangered and Threatened Wildlife. Please see the February 16, 2016, proposed rule (81 FR 7723) for a detailed discussion of the recovery goal, objectives, and criteria and how they apply to the status of the San Miguel Island fox, Santa Rosa Island fox, Santa Cruz Island fox, and Santa Catalina Island fox. The objectives and progress toward these objectives (measured by explicit criteria) are summarized below.

Recovery Objectives

Recovery objectives identify mechanisms for measuring progress toward and achieving the recovery goal of delisting for each subspecies.

Recovery Objective 1: Each federally listed subspecies of island fox exhibits demographic characteristics consistent with long-term viability.

Recovery Objective 2: Land managers are able to respond in a timely fashion to predation by nesting golden eagles (*Aquila chrysaetos*) or significant predation rates by transient golden eagles, to potential or incipient disease outbreaks, and to other identified threats using the best available technology.

In order for any one of the four listed subspecies of island fox to be considered for downlisting from endangered to threatened status, recovery objective 1 should be met for that subspecies. In order for any one of the four listed subspecies of island fox to be considered for delisting, recovery objectives 1 and 2 should be met for that subspecies.

Island fox recovery criteria are measurable standards for determining whether a subspecies has achieved its recovery objectives and may be considered for downlisting or delisting. Island fox recovery criteria in the recovery plan (Service 2015, pp. 50–55) are organized by factors under section 4(a)(1) of the Act to demonstrate how criteria indicate threats under that factor have been ameliorated. The following is a summary of the recovery criteria.

To address recovery objective 1, the subspecies must be protected from other natural or manmade factors known to affect their continued existence. This is accomplished when the following has occurred:

E/1: An island fox subspecies has no more than 5 percent risk of quasi-extinction over a 50-year period as determined by use of the population viability graphing/analysis tool found in appendix 2 of the recovery plan (Service 2015, pp. 131–136).

To address recovery objective 2, the magnitude and imminence of disease and predation threats must be reduced. This is accomplished when the following has occurred:

C/1: Golden eagle predation (applies only to the northern Channel Islands): The rate of golden eagle predation is reduced and maintained at a level no longer considered a threat to island fox recovery through development of a golden eagle management strategy, and the golden eagle prey base of mule deer (*Odocoileus hemionus*) and Roosevelt elk (*Cervus canadensis roosevelti*) is removed from Santa Rosa Island.

C/2: Disease: A disease management strategy is developed, approved, and implemented that includes vaccination recommendations and a monitoring program that provides for timely detection of a potential epidemic, and an associated emergency response strategy as recommended by the appropriate subject-matter experts.

Population monitoring has been implemented for each listed subspecies, and population viability analyses using the graphing/analysis tool found in appendix 2 of the recovery plan (Service 2015, pp. 131–136) indicate all subspecies have an acceptably small risk of extinction. The extinction risk has been less than 5 percent since 2008 for San Miguel, Santa Cruz, and Santa Catalina Islands, and since 2011 for Santa Rosa Island. As of 2015, island fox populations had increased to greater than 700 individuals on San Miguel Island, greater than 1,200 on Santa Rosa Island (Guglielmino and Coonan 2016, pp. 12, 18), greater than 2,100 on Santa Cruz Island (Boser 2016a, pers. comm.), and greater than 1,800 on Santa Catalina Island (King and Duncan 2016, p. 10). All populations with the exception of Santa Rosa Island are at or above their pre-decline population estimates (Coonan 2015a, pers. comm.; King and Duncan 2014, pp. 1, 10). On San Miguel Island, low reproductive effort coupled with declining survival suggests that the San Miguel Island subspecies has reached carrying capacity (the maximum population size of a species that the habitat can support) (Coonan 2015a, p. 8). We conclude, based on population viability analyses, that recovery objective 1 is achieved for all four island fox subspecies. Detailed results of the graphing/analysis tool through 2015 can be found in the supplementary material "Results of graphing/analysis tool to assess island fox recovery criterion E/1" (derived from Guglielmino and Coonan 2016, pp. 17, 22; Boser 2016b, pers. comm.; King and Duncan 2016, p. 13) on the Internet at *http://www.regulations.gov* at Docket No. FWS–R8–ES–2015–0170.

To ensure that land managers are able to respond in a timely fashion to predation by golden eagles, a final golden eagle management strategy has been approved (NPS 2015a, entire), and is being implemented by NPS and TNC. The strategy outlines actions, many of which have already been implemented by NPS and TNC, including: Complete removal of all golden eagles; ongoing prevention of golden eagle nesting; and removal of all nonnative golden eagle prey, including deer and elk from Santa Rosa Island.

To ensure that land managers are able to respond in a timely fashion to a potential or incipient disease outbreak, the epidemic response plans for northern Channel Islands foxes (Hudgens *et al.* 2013, entire) and Santa Catalina Island foxes (Hudgens *et al.* 2014, entire) are currently implemented by NPS, TNC, and CIC. These plans provide direction for monitoring, vaccination for canine distemper virus and rabies annually to a subset of each island fox population, and response if mortality is detected. Additionally, NPS and TNC are committed through signed conservation management agreements (CMAs) to monitor and conduct other management actions for detecting and appropriately responding to predation by golden eagles or a potential disease outbreak in the future, as recommended in the golden eagle management strategy and epidemic response plans (Service and NPS 2015; Service and TNC 2015). The golden eagle management strategy and epidemic response plans are found on the Internet at *http://www.regulations.gov* at Docket No. FWS–R8–ES–2015–0170 and on our Endangered Species Program's national Web site (*http://endangered.fws.gov*).

With the golden eagle management strategy in place, complete removal of golden eagles and their nonnative prey-base from the northern Channel Islands (San Miguel, Santa Rosa, and Santa Cruz Islands), development and implementation of an epidemic response plan, and population levels consistent with long-term viability, recovery objectives 1 and 2, and the associated recovery criteria, are met for the San Miguel, Santa Rosa, and Santa Cruz Island foxes. With population levels consistent with long-term viability, recovery objective 1 is met for the Santa Catalina Island fox. However, objective 2 has not been met for the Santa Catalina Island fox because currently there are no assurances that current monitoring and management actions will continue in the future, and, because Santa Catalina Island has an elevated risk compared to the northern Channel Islands of introduced pathogens from the mainland, a disease outbreak could occur without detection or appropriate response to mediate the threat to the subspecies.

Summary of Factors Affecting the Species

Section 4 of the Act and its implementing regulations (50 CFR part 424) set forth the procedures for listing species, reclassifying species, or removing species from listed status. "Species" is defined by the Act as including any species or subspecies of fish or wildlife or plants, and any distinct population segment of any species of vertebrate fish or wildlife which interbreeds when mature (16 U.S.C. 1532(16)). A species may be determined to be an endangered species or threatened species because of any one or a combination of the five factors described in section 4(a)(1) of the Act: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or human-made factors affecting its continued existence. A species may be reclassified or delisted on the same basis.

A recovered species is one that no longer meets the Act's definition of an endangered species or a threatened species. Determining whether a species is recovered requires consideration of whether the species is endangered or threatened because of the five categories of threats specified in section 4(a)(1) of the Act. For species that are already listed as endangered or threatened species, this analysis of threats is an evaluation of both the threats currently facing the species and the threats that are reasonably likely to affect the species in the foreseeable future following the delisting or downlisting and the removal or reduction of the Act's protections.

A species is an "endangered species" for purposes of the Act if it is in danger of extinction throughout all or a significant portion of its range and is a "threatened species" if it is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The Act does not define the term "foreseeable future." The population viability analyses used to determine the risk of quasi-extinction (the population level below which extinction is likely due to demographic or genetic effects), which we define as a population size of less than or equal to 30 individuals for each subspecies, estimates risk over a 50-year period (Bakker *et al.* 2009, entire; Service 2015, p. 52). Therefore, we estimate 50 years to be the timeframe in which, given the amount and substance of the best available data, we can anticipate events or effects, or reliably extrapolate threat trends, concerning the future as it relates to the status of the four subspecies of island fox (San Miguel, Santa Rosa, Santa Cruz, and Santa Catalina Island foxes). Consequently, we have assessed the threats discussed in this rule with reference to this 50-year foreseeable future timeframe.

The word "range" in the significant portion of its range phrase in the definition of endangered species and threatened species refers to the range in which a species currently exists. For the purposes of this analysis, we first evaluate the status of each subspecies throughout its range, which we consider to be the island that any given island fox subspecies inhabits. We then consider whether any of the subspecies are in danger of extinction or likely to become so in any significant portion of their ranges.

Primary threats to island foxes identified in the March 5, 2004, listing rule (69 FR 10335) include predation by golden eagles, disease, and stochastic risks to small populations and lack of genetic variability. Since the listing, impacts of feral cat aggression, poisoning, and entrapment on Santa Catalina Island, and fire, drought, and global climate change for all four islands were identified as possible new threats. A thorough analysis and discussion of the current status of the San Miguel, Santa Rosa, Santa Cruz, and Santa Catalina Island foxes are found in the recovery plan (Service 2015, pp. 21–29) and proposed rule to remove the San Miguel Island fox, Santa Rosa Island fox, and the Santa Cruz Island fox from the Federal List of Endangered and Threatened Wildlife, and to reclassify the Santa Catalina Island fox from an endangered species to a threatened species (81 FR 7723; February 16, 2016). The following sections provide a summary of the past, current, and potential future threats impacting the San Miguel, Santa Rosa, Santa Cruz, and Santa Catalina Island foxes.

Factor A: Present or Threatened Destruction, Modification, or Curtailment of Habitat or Range

At the time of listing in 2004, habitat modification by nonnative grazing animals (*i.e.,* feral sheep, goats, rabbits, cattle, horses, Roosevelt elk, mule deer, and pigs) and nonnative plant invasion was identified as a threat under Factor A impacting island foxes (69 FR 10335; March 5, 2004). The impacts of nonnative herbivores and nonnative plants resulted in conversion of native coastal sage scrub, chaparral, and oak woodlands to annual grasses. Annual grasslands constitute less preferred habitat for island foxes (Laughrin 1977, p. 22; Roemer and Wayne 2003, pp. 1,256–1,257) and do not provide cover from predators such as golden eagles (Roemer 1999, pp. 99, 190–191). Annual grasslands also offer fewer food resources to foxes, and the seeds of annual grasses can become lodged in the eyes of island foxes, causing damage or temporary blindness (Laughrin 1977, p. 41).

Eradication programs on all islands have greatly reduced the number of nonnative herbivores on the islands and therefore the magnitude of impacts to the habitat and island foxes (Laughrin 1973, p. 14; Schoenherr *et al.* 1999, pp. 191–194; Parkes *et al.* 2010, p. 636; Jones *et al.* 2016, p. 2). Currently, impacts to island fox habitats are primarily attributed to continued modification by nonnative plant species, resulting in lower vegetation diversity, less diverse habitat structure, and reduced food availability.

NPS guidance supports the continued management of island fox habitat to benefit northern Channel Islands subspecies of island foxes. Title 54 of the U.S. Code, section 100101, paragraph (a), states that the NPS "shall promote and regulate the use of the National Park System . . . to conserve the scenery, natural and historic objects, and wild life in the System units and to provide for the enjoyment of the scenery, natural and historic objects, and wild life in such manner and by such means as will leave them unimpaired for the enjoyment of future generations." Specifically, in its management plan, Channel Islands National Park identified restoration and maintenance of natural ecosystems and processes as a priority; NPS staff would continue to eradicate, where feasible, nonnative flora and fauna from the islands.

The majority of island fox habitat on all four islands is currently in some form of conservation ownership and management by NPS, TNC, or CIC. Therefore, we expect that habitat loss as a result of conversion due to development would be rare or limited. However, there is the potential for some development on privately owned lands that are not in conservation ownership. The island fox, as the species *Urocyon littoralis* (incorporating all six subspecies), is listed as threatened under the California Endangered Species Act (CESA), which provides a level of protection from possession or intentional killing of individual animals. CESA may also authorize take incidental to otherwise lawful activities, such as development on the privately owned TNC-managed lands on Santa Cruz Island and privately owned lands on Santa Catalina Island. For habitat conversion resulting from authorized development projects, minimization and mitigation of impacts resulting from authorized take are required under CESA and the environmental review process under the California Environmental Quality Act. Santa Catalina Island foxes are most likely to be impacted by the potential for land-use change on non-conserved lands, including development and recreational activities. CESA contributes to the conservation of the species by providing a mechanism to reduce or regulate some individual sources of mortality and to review and permit development projects that may impact island foxes and their habitat on private lands.

While past and ongoing effects of habitat modification by nonnative grazing animals (*i.e.,* feral sheep, cattle, Roosevelt elk, mule deer, and pigs), nonnative plant invasion, and land-use change on non-conserved lands may continue to have some negative effects on island foxes, nonnative animals and plants no longer result in significant habitat impacts that could affect the island fox subspecies at either the population or rangewide scales that we would consider a current threat to any of the subspecies of island fox.

Additionally, given planned continued management by NPS and other land owners, we do not anticipate that nonnative animals and plants will have significant habitat impacts in the future.

Factor B: Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

As stated in the listing rule (69 FR 10335; March 5, 2004), although island foxes were used in the past for their pelts by Native Americans (Collins 1991, p. 215), these activities no longer occur. Research scientists are currently engaged in recovery activities via Service-issued section 10(a)(1)(A) recovery permits. Researchers conducting studies on NPS property must have a valid Research and Collecting Permit through NPS. The State of California requires a Scientific Collecting Permit and Memorandum of Understanding to collect, capture, mark, or salvage species listed as threatened under CESA for scientific and educational purposes (Fish and Game Code section 1002; and title 14, sections 650 and 670.7). Currently, none of the four subspecies is being threatened by overutilization for any purposes, and we expect, even without the protections of the Act, research activities to be managed by the State and by land management agencies to ensure that such activities do not result in overutilization in the future.

Factor C: Disease or Predation

For Santa Catalina Island fox at the time of listing, a canine distemper virus (CDV) epidemic was considered the primary threat (69 FR 10335; March 5, 2004) to the subspecies. The listing rule also expressed some concern regarding the potential impacts of canine adenovirus and canine parvovirus. For the northern Channel Islands foxes (San Miguel, Santa Rosa, and Santa Cruz Island foxes) at the time of listing, golden eagle predation was the primary threat (69 FR 10335; March 5, 2004), but potential for disease was also a concern, particularly given the small population sizes at the time.

Disease

Santa Catalina Island: In the past, disease severely impacted the island fox population on Santa Catalina Island. The eastern subpopulation of the Santa Catalina Island fox was estimated to be 1,342 in 1990 (Roemer *et al.* 1994, p. 393). Subsequent surveys conducted in 1999 and 2000 indicated the eastern island fox subpopulation had declined by over 90 percent in 10 years due to CDV (Timm *et al.* 2000, p. 17), likely transmitted from a raccoon that arrived from the mainland (Timm *et al.* 2009, p. 339). After a captive-rearing and augmentation program was initiated, the eastern and western subpopulations were estimated to have reached 219 and 141 foxes in 2004, respectively (Schmidt *et al.* 2005, p. 11; King and Duncan 2011, p. 19). Population estimates have since greatly increased on Santa Catalina Island, surpassing the estimate from 1990, reaching a total of 1,812 individuals island-wide in 2015 (King and Duncan 2016, p. 10).

In 2014, a final epidemic response plan was approved and is being implemented by CIC to detect and facilitate appropriate response to a potential future disease outbreak for Santa Catalina Island foxes (Hudgens *et al.* 2014, entire). CIC annually monitors sentinel foxes (unvaccinated, radio-collared foxes whose death will be detected by monitoring) inhabiting many areas of the island to facilitate early detection of a potential epidemic (King and Duncan 2011, p. 15). Island foxes have been and continue to be vaccinated against CDV and rabies (King 2015, pers. comm.). However, production of the CDV vaccine was discontinued and was not available in 2013. CIC vaccinated for both CDV and rabies in 2013 and 2014 with the last of the vaccine (King and Duncan 2015, pp. 13, 23). A new product was made available in 2015 (King and Duncan 2016, p. 9); however, the new vaccine does not appear to be as effective against CDV, and the authors suggest this is not an adequate replacement (King and Duncan 2016, p. 23). While foxes have been vaccinated and we expect vaccinations to continue as effective vaccines become available, efficacy and availability of vaccines will require ongoing evaluation by the Island Fox Conservation Working Group as part of implementing the epidemic response plan. The Island Fox Conservation Working Group is a multi-disciplinary group of experts, originally convened by NPS in 1999, to evaluate available island fox status information and develop strategies to recover the island fox populations to viable levels (Service 2015, p. 6).

In addition, ear tumor prevalence in the Santa Catalina Island fox population remains an actively managed source of mortality (Vickers *et al.* 2011, pp. 9–10). This cancer can have an aggressive clinical course, with local invasion, tissue damage, and metastasis, leading to death (Munson *et al.* 2009, p. 1). Ear inflammation correlated with cancer incidence in Santa Catalina Island foxes is triggered by ear mite infestations (Munson *et al.* 2009, pp. 3–4), and the severity can be reduced through aracacide application (Vickers *et al.* 2011, pp. 9–10). Treatment with aracacide is now standard practice by CIC during trapping of Santa Catalina Island foxes (King and Duncan 2011, p. 3).

While CIC is currently implementing ongoing monitoring and management, at this time there is no assurance of continued funding for long-term monitoring and management that could detect a novel disease outbreak and facilitate threat abatement, as recommended in the epidemic response plan. Lack of assurances for long-term monitoring and management for Santa Catalina Island fox is of particular concern because the island has a permanent human population, experiences heavy visitation, and has many points of access. The presence of a permanent human population on the island poses a greater risk of disease introduction than that for the northern Channel Islands. CIC manages the majority of fox habitat on the island but does not manage the City of Avalon, and, therefore, CIC does not control all potential avenues for introduction of possible disease vectors. Santa Catalina Island currently allows visitors and residents to own and transport pets, including domestic dogs and cats, to and from the island (King and Duncan 2011, p. 15), and dogs are frequently observed off-leash (Anderson 2012, pers. obs.; King 2012a, p. 1; Vissman and Anderson 2013 and 2014, pers. obs.; King 2015, p. 22). Transport of domestic and wild animals to and from Santa Catalina Island and their presence on the island increases the risk to island foxes of another disease outbreak. Additionally, with unrestricted access to the island by residents and visitors, there is the possibility of inadvertently transporting other animals that could carry disease; to date, four stowaway raccoons have been removed from the island, but a fifth observed in 2010 was not captured (King and Duncan 2011, p. 15). There is no quarantine period for transported pets, and proof of current vaccination is only required by the City of Avalon when licensing dogs (rabies only), and for CIC employees and lessees with pets living in company-owned housing (King and Duncan 2011, p. 15). Because access to the island by potentially unvaccinated or incompletely vaccinated domestic animals is not controlled or managed, there is a higher risk of disease introduction for Santa Catalina Island than for the three northern Channel Islands.

CIC manages the majority of fox habitat on the island (but not the City of Avalon) and implements measures intended to control introduction of disease. CIC regulations require all nonnative animals entering CIC property be licensed; they also require that all dogs and cats entering CIC property be vaccinated against distemper and rabies, and be leashed at all times (CIC 2015, *http://www.catalinaconservancy.org*). However, enforcement of CIC regulations is labor-intensive and costly, because the island is large, there are many remote coves and beaches where private boats can anchor, and CIC does not have the funding or staff to patrol these areas regularly. CIC also conducts outreach and education of local authorities and the public to promote efforts to reduce the risk of disease introduction. However, because of unrestricted transport of domestic animals to the island, the City of Avalon's limited vaccination requirements, and limited enforcement ability of CIC, current measures to control introduction of diseases by domestic animals and stowaway wildlife on Santa Catalina Island, while providing some protection, are limited.

Northern Channel Islands: Disease does not appear to be a significant mortality factor on the northern Channel Islands. Dogs and other pets are not permitted on the northern Channel Islands to reduce the risk of an introduced disease. Dogs are occasionally illegally brought onto the islands, but transport of domestic animals to the northern Channel Islands is much more limited than on Santa Catalina Island. Channel Islands National Park General Management Plan prohibits pets from all Park islands, except for guide dogs for visually impaired persons (NPS 2015b, pp. 468, 487).

In 2013, a final epidemic response plan was approved and is being implemented by NPS and TNC to detect and facilitate appropriate response to a potential disease outbreak for the northern Channel Islands (Hudgens *et al.* 2013, entire). Infection by parasites continues to be suspected as the cause of mortality in several island foxes, but is not considered a significant mortality factor (Coonan *et al.* 2005b, p. 38; Coonan 2014, p. 6). Sentinel foxes are also monitored on the northern Channel Islands to facilitate early detection of a potential epidemic (Hudgens *et al.* 2013, entire), and foxes have been and continue to be vaccinated against CDV and rabies. Efficacy and availability of vaccines will require ongoing evaluation by the Island Fox Conservation Working Group as part of implementing the epidemic response plan. Also, the NPS identified island foxes as an ecosystem element in the Mediterranean Coast Network Vital Signs Monitoring Plan, for which they will conduct long-term annual population monitoring as part of NPS's long-term ecological monitoring program, regardless of the island fox's status under the Act (Cameron *et al.* 2005, p. 3–3). Both NPS and TNC have committed through signed CMAs (Service and NPS 2015; Service and TNC 2015) to carrying out monitoring and management actions in the future as recommended in the epidemic response plan for northern Channel Island foxes (Hudgens *et al.* 2013, entire).

In summary, the possibility exists for domestic or wild animals carrying a disease or parasite to migrate or be transported to all the Channel Islands. The possibility is greater for Santa Catalina Island due to a permanent human population, heavy visitation, and many points of access. On all islands, an epidemic response plan is approved and being implemented (Hudgens *et al.* 2013 and 2014, entire), which includes that a subset of foxes are vaccinated when vaccines are available and monitored to detect and respond to a potential disease outbreak (Coonan 2010, pp. 24–29; see appendices 3 and 4 in recovery plan (Service 2015)). NPS and TNC have committed (Service and NPS 2015; Service and TNC 2015) to carrying out monitoring and management actions in the future as recommended in the epidemic response plan for northern Channel Island foxes (Hudgens *et al.* 2013, entire); therefore, we consider the potential threat of disease adequately controlled for the San Miguel, Santa Rosa, and Santa Cruz Island foxes now and in the future. We do not at this time have the assurance of continued implementation of the epidemic response plan on Santa Catalina Island. Disease was the main threat to Santa Catalina Island foxes at the time of listing in 2004, and given the increased risk of disease introduction and the lack of assurance for continued implementation of the epidemic response plan to detect and mitigate for future disease outbreaks, we still consider potential disease outbreaks to be a threat to the Santa Catalina Island fox now and in the future.

Predation

As identified in the 2004 listing rule, golden eagle predation was the primary cause for the decline of the northern Channel Islands fox subspecies and the primary reason for listing the species as endangered under the Act (69 FR 10335; March 5, 2004). Before golden eagles started using the northern Channel Islands in the 1990s, the only known predator of island foxes was the red-tailed hawk (*Buteo jamaicensis*), which preyed only occasionally on young island foxes (Laughrin 1973, pp. 10–11; Moore and Collins 1995, p. 4). Because of the lack of predators, island foxes did not evolve vigilance and were easy targets for golden eagles (Roemer *et al.* 2001, p. 316). Colonization of the northern Channel Islands by golden eagles was likely a combination of two factors: (1) Introduction of nonnative mammals on the northern Channel Islands, resulting in a historically unprecedented prey base for golden eagles (69 FR 10335, March 5, 2004, p. 10338); and (2) an open ecological niche created by the extirpation of bald eagles (*Haliaeetus leucocephalus*) from the islands as a result of dichlorodiphenyltrichloroethane (DDT) poisoning (Service 2004, p. 10343).

In the 2004 listing rule, the Federal Bald and Golden Eagle Protection Act (BGEPA; 16 U.S.C. 668–668d) and the California Fish and Game Code, section 3511, were thought to have delayed or precluded the implementation of needed recovery actions for island foxes. The protections afforded to golden eagles by the BGEPA were thought to limit lethal management alternatives to protect island foxes. The California Fish and Game Code, section 3511, deemed golden eagles a fully protected species, which did not allow any take to be authorized. In 2003, California amended this law to allow authorization of the take of fully protected species for scientific research, including research on recovery for other imperiled species (Senate Bill 412).

To address the unprecedented number of golden eagles and the effects they were having on island foxes, in August 1999, NPS and TNC initiated a nonlethal golden eagle removal program to protect island foxes on the northern Channel Islands. Between November 1999 and July 2006, 44 golden eagles, including 22 adults or near adults, were removed from Santa Rosa and Santa Cruz Islands and released in northeastern California (Latta *et al.* 2005, p. 348; Coonan *et al.* 2010, pp. 59–61). There has been no record of breeding golden eagles on the northern Channel Islands since that time.

To ensure that golden eagles would be less likely to attempt to establish territories again on Santa Rosa and Santa Cruz Islands, TNC and NPS initiated a program in 2005 and 2011, respectively, to remove nonnative animals from those islands (Macdonald and Walker 2007, p. 20). The last known feral pig was removed from Santa Cruz Island in January 2007 (Parkes *et al.* 2010, p. 636). Nonnative mule deer and elk were removed from Santa Rosa

Island as part of an agreement with the former owners of the island. All elk and all but a few deer were removed by 2015, resulting in an island that was essentially ungulate-free for the first time in over 150 years (Coonan 2015b, pers. comm.).

The 2004 listing rule also identified the extirpation of bald eagles from the Channel Islands as a likely contributor to the colonization of the northern Channel Islands by golden eagles. Bald eagles aggressively defend their territories from golden eagles (69 FR 10335, March 5, 2004, pp. 10343–10344), and their presence on the islands likely would have discouraged dispersing golden eagles from establishing residence. Prior to listing, NPS, the Institute for Wildlife Studies, and TNC were actively engaged in the Montrose Settlements Restoration Program to reintroduce bald eagles to the Channel Islands, including Santa Catalina Island. The success of bald eagle reintroduction on the Channel Islands continues, with approximately 50 total resident bald eagles on the islands (Montrose Settlements Restoration Program 2015, p. 1).

In summary, although golden eagle predation of island foxes may occasionally occur (Coonan *et al.* 2014a, p. 374), predation has been extensively reduced and is no longer resulting in significant impacts at the population scale. This reduction in predation by golden eagles is in direct response to the extensive removal of golden eagles from the northern Channel Islands, golden eagle prey being removed successfully from Santa Rosa and Santa Cruz Islands, and the successful reintroduction of bald eagles.

Summary of Factor C

To reduce the threat of disease, a subset of each island fox subspecies is protected from CDV and rabies through preventative vaccinations when available and through monitoring as recommended in epidemic response plans to detect and facilitate appropriate responses in the event of an epidemic. NPS and TNC are committed through signed conservation management agreements (CMAs) to monitor and conduct other management actions for detecting and appropriately responding to a potential disease outbreak in the future, as recommended in the epidemic response plans (Service and NPS 2015; Service and TNC 2015). Therefore, the best available data indicate potential disease outbreaks are no longer a threat to the Santa Rosa Island fox, San Miguel Island fox, and Santa Cruz Island fox now and in the future.

Mortality due to disease was the primary reason for the decline and listing of Santa Catalina Island foxes. Currently, the epidemic response plan is being implemented on Santa Catalina Island, but the potential for an epidemic remains on Santa Catalina Island because of heavy visitation, many points of access, and few controls for pets and stowaway wild animals that could carry disease. In addition, there is no assurance of continued implementation of the epidemic response plan in the future on Santa Catalina Island to detect and mitigate for future disease outbreaks, and the new CDV vaccine may not be adequate. Efficacy and availability of vaccines will require ongoing evaluation by the Island Fox Conservation Working Group as part of implementing the epidemic response plan. Overall, the best available data indicate potential disease outbreaks to be a threat to the Santa Catalina Island fox now and in the future.

Mortality due to golden eagle predation was the primary reason for the decline and listing of northern Channel Islands foxes (San Miguel, Santa Rosa, and Santa Cruz Island foxes). This threat has been substantially reduced by measures including the complete removal of golden eagles, eradication of golden eagles' nonnative prey, and reintroduction of bald eagles. Additionally, NPS and TNC are committed through signed CMAs to monitor and conduct other management actions for detecting and appropriately responding to predation by golden eagles in the future, as recommended in the golden eagle management strategy (Service and NPS 2015; Service and TNC 2015). Thus, given the recent golden eagle and prey-base eradication efforts and reintroduction of bald eagles to prevent golden eagle presence in the future, along with ongoing management commitments, we no longer consider predation by golden eagles to be a threat resulting in significant impacts at the population scale (*e.g.,* result in a population decline) on the northern Channel Islands now or in the future.

Factor D: The Inadequacy of Existing Regulatory Mechanisms

Under this factor, we examine whether existing regulatory mechanisms are inadequate to address the threats to the four island fox subspecies discussed under other factors. Section 4(b)(1)(A) of the Act requires the Service to take into account "those efforts, if any, being made by any State or foreign nation, or any political subdivision of a State or foreign nation, to protect such species." In relation to Factor D under the Act, we interpret this language to require us to consider relevant Federal, State, and Tribal laws, regulations, and other such mechanisms that may minimize any of the threats we describe in the threats analyses under the other four factors, or otherwise enhance conservation of the species. We give strongest weight to statutes and their implementing regulations and to management direction that stems from those laws and regulations; an example would be State governmental actions enforced under a State statute or constitution, or Federal action under statute.

For currently listed species, we consider the adequacy of existing regulatory mechanisms to address threats to the species absent the protections of the Act. Therefore, we examine whether other regulatory mechanisms would remain in place if the species were delisted, and the extent to which those mechanisms will continue to help ensure that future threats will be reduced or minimized.

In our discussion under Factors A, B, C, and E, we evaluated the significance of the threat as mitigated by any such conservation efforts and existing regulatory mechanisms. Where threats exist, we analyze under Factor D the extent to which existing regulatory mechanisms are inadequate to address the specific threats to the species. Regulatory mechanisms, if they exist, may reduce or eliminate the impacts from one or more identified threats.

As noted in our discussion under the other factors, conservation measures and existing regulatory mechanisms (such as continued implementation of the epidemic response plan and golden eagle management strategy) have reduced the primary threats of disease and predation by golden eagles on the northern Channel Islands and will continue to be controlled through appropriate management. Other previously identified threats affecting the San Miguel Island fox, Santa Rosa Island fox, Santa Cruz Island fox, and Santa Catalina Island fox, such as habitat modification by nonnative grazing animals and nonnative plant invasion and habitat conversion (Factor A), have been and are continuing to be controlled through appropriate management, and we anticipate that these efforts will continue in the future. Other sources of mortality are assessed under Factor E and found to not exert significant impacts on island foxes at either the population or rangewide scales, now or in the future. Consequently, we find that conservation measures along with existing regulatory mechanisms are adequate to address these specific threats.

The remaining threat to island fox on Santa Catalina Island is the potential for a disease epidemic because of heavy visitation, many points of access, and few controls for pets and stowaway wild animals that could carry disease. In addition, we do not have the assurance of continued implementation of the epidemic response plan in the future on Santa Catalina Island to detect and mitigate for future disease outbreaks. Therefore, under Factor C, we still consider potential disease outbreaks to be a threat to the Santa Catalina Island fox at this time and in the future. Consequently, our analysis here examines how existing regulatory mechanisms address this remaining identified threat to the Santa Catalina Island fox.

There are currently no regulations restricting transport of domestic animals to the island, and limited vaccination requirements for domestic animals owned by City of Avalon residents, thus providing the potential for introduction of disease to the island. CIC manages the majority of fox habitat on Santa Catalina Island, but not the City of Avalon; CIC regulations require all nonnative animals entering CIC property be licensed and that all dogs and cats be vaccinated against distemper and rabies (CIC 2015, entire). Reduction of the risk of disease introduction also occurs through CIC outreach and education of local authorities and the public. However, enforcement of CIC regulations is labor-intensive and costly because the island is large with many remote coves and beaches where private boats can anchor, and CIC does not have the funding or staff to patrol these areas regularly. Therefore, current measures to control introduction of diseases by domestic animals and stowaway wildlife on Santa Catalina Island, while providing some protection, are limited and thus do not fully address the threat of disease to Santa Catalina Island fox (see Factor C discussion, above).

Summary of Factor D

In summary, we have discussed that the threats previously facing the three northern Channel Islands subspecies of island fox have been removed or reduced and are being adequately managed; however, disease remains a threat to the Santa Catalina Island fox. In examining how existing regulatory mechanisms address this identified threat, we find current measures to control introduction of diseases by domestic animals and stowaway wildlife on Santa Catalina Island, while providing some protection, are limited in addressing the threat of potential disease outbreaks to Santa Catalina Island fox. Therefore, we still consider potential disease outbreaks to be a threat to the Santa Catalina Island fox now and in the future under Factor C, noting that this threat is not addressed by existing regulatory mechanisms.

Factor E: Other Natural or Manmade Factors Affecting Its Continued Existence

The 2004 listing rule identified stochastic risks to small populations and lack of genetic variability as threats to all four island fox subspecies under Factor E (69 FR 10335; March 5, 2004). Road mortalities were also discussed under Factor E in the 2004 listing rule. Since the time of listing, the impacts of feral cat aggression, poisoning, and entrapment on Santa Catalina Island, as well as fire, drought, and global climate change for all four islands, have been identified as possible new threats.

Small Population Size

Island endemics, such as island foxes, have a high extinction risk due to isolation and small total population sizes relative to mainland subspecies (MacArthur and Wilson 1967, entire), both of which make them more vulnerable, especially to stochastic events such as drought and wildfire (Miller *et al.* 2001, entire; Kohlman *et al.* 2005, entire). Each island fox subspecies is a single breeding population, with San Miguel Island being the smallest population, which makes their populations inherently small and thus they may become more vulnerable to extinction when the size of a breeding population declines. In addition to small population size and the associated increased probability of extinction, lower and reduced genetic variation may make an island species less adapted to existing pressures and less capable of adaptation to new threats. Thus, small population size and low genetic diversity can have synergistic effects with respect to population decline. During the period when the island fox populations were at their lowest, they were extremely vulnerable to extinction from stochastic events. The populations have now increased substantially, returning to historical population levels, and the threat of extinction from demographic stochasticity has accordingly been reduced.

Genetic diversity in island fox populations is considered low due to the population bottlenecks they experienced during past extreme, low population numbers (Gilbert *et al.* 1990; Wayne *et al.* 1991; Goldstein *et al.* 1999; Gray *et al.* 2001, p. 8; Gray 2002, entire; Aguilar *et al.* 2004; Funk *et al.* 2016, p. 11; Wayne *et al.* 2016, p. 4). This low genetic diversity could compromise the ability of island foxes to respond to future environmental change. This lack of variability could be attributed either to extensive inbreeding or to bottlenecking resulting from low population densities (Funk *et al.* 2016, p. 11). However, island foxes have apparently existed for thousands of years with low effective population sizes (the number of individuals that can contribute genes equally to the next generation; low is defined as 150 to 1,000) and low genetic variability (Wayne *et al.* 1991a, p. 1,858; 1991b, entire). While additional genetic diversity was lost during the recent declines, island foxes appear to be tolerant of low genetic variation, occasional bottlenecks, and higher inbreeding because there is little evidence of inbreeding depression in island foxes (Coonan *et al.* 2010, pp. 13–15). Therefore, we do not consider reduced genetic diversity to be causing population-level effects at this time or expect it to in the future.

Motor Vehicles

The fearlessness of island foxes, coupled with relatively high vehicle traffic on Santa Catalina Island, results in multiple fox collisions each year. On the northern Channel Islands, vehicle use is limited, restricted to only land management personnel and researchers, and is expected to remain limited into the future. On Santa Catalina Island, 10 of the 21 fox mortalities in 2015 were caused by vehicle strikes (King and Duncan 2016, p. 18). The island-wide 25 mile per hour speed limit (CIC 2015, no page number) likely minimizes the number of vehicle strike mortalities that would otherwise occur. Even with current mortality of island foxes caused by various factors including vehicle strikes, the Santa Catalina Island fox population showed significant growth between 2002 and 2015, and has hovered around 1,800 individual foxes for the past 3 years. Given island fox population growth over the past 13 years during a time when the number of vehicles on the road has increased, we do not expect the population effect from vehicle mortality to increase in the future. Additionally, there is less than a 5 percent chance of the Santa Catalina Island fox subspecies going extinct given current and expected future conditions (King and Duncan 2016, pp. 12–13; Service 2015, pp. 167–168). Therefore, even though vehicle strikes remain the primary human-caused source of individual mortality on this island, mortality by motor vehicles is not considered a threat resulting in significant impacts at either the population or rangewide scales on Santa Catalina Island at this time or in the future.

Interactions With Feral Cats and Domestic Dogs

Feral cats and domestic dogs occur on Santa Catalina Island and may negatively affect foxes through interactions including direct aggression and competition for food and habitat resources (Laughrin 1978, pp. 5–6; Kovach and Dow 1981, p. 443). Direct aggression between Santa Catalina Island foxes and cats has been documented in the wild, primarily near public coves and campgrounds that provide food and shelter for feral cats (Guttilla 2007, p. 9). Researchers have routinely captured foxes that have severe injuries consistent with cat encounters (Guttilla 2007, p. 9). Aggressive exclusion of foxes by feral cats has also been observed. When cats move into fox habitat, foxes are no longer observed; when cats are no longer resident, foxes move back in to occupy the area (King 2013c, pers. comm.; Anderson 2013, pers. obs.).

In the 2004 listing rule (69 FR 10335; March 5, 2004), we noted that California's Food and Agricultural Code 31752.5 prohibited lethal control of feral cats unless cats are held for a minimum of 6 days, which was thought to prevent CIC from taking steps to eradicate feral cats on Santa Catalina Island. In 2008, a Feral Animal Task Force was convened by the City of Avalon, with representatives of CIC and other island stakeholders, to address feral and free-ranging cats in the city and on the rest of the island, and most importantly, to draft legislation for consideration by the City Council for approval and incorporation into City ordinance. This task force is not currently active, however, and progress has stalled in initiating new feral cat control measures and enacting new legislation (King 2016, pers. comm.). Currently, the CIC practice regarding feral cats is consistent with that of the Catalina Island Humane Society: animals trapped accidentally during fox-trapping/monitoring are examined, and, if free from incurable and contagious disease, are spayed or neutered and released. Animals found to test positive for Feline Leukemia or Feline Immunodeficiency are humanely euthanized. Younger cats including kittens may be adopted from the Catalina Island Humane Society (CIC 2016, *http://www.catalinaconservancy.org*). Although competition and other negative interactions with feral cats can affect individual foxes, they are not currently resulting in significant impacts at either the population or rangewide scales.

Instances of fox mortality from domestic dog attacks have been observed over the past decade (Gaffney 2011, p. 1; Munson and Gaffney 2011, p. 1; King and Duncan 2011, pp. 12–13; King and Duncan 2012, p. 14; King 2012a, p. 1; 2012b, p. 1; King 2015, p. 1). While mortality due to domestic dog attacks has been reported, it is limited in effect to individual foxes, and does not have significant impacts to island fox at either the population or rangewide scales now nor do we anticipate that it will in the future.

We do not anticipate an increase in the number of feral cats and domestic dogs on Santa Catalina Island in the future. Because growth of the Santa Catalina Island fox population over the past 13 years occurred during a time when feral cats and foxes and domestic dogs and foxes have been interacting, we do not expect that interactions with feral cats or domestic dogs will result in negative population effects in the future. Overall, given the lack of significant impacts at either the population or rangewide scales, interactions with feral cats and domestic dogs are not considered a threat to the Santa Catalina Island fox now or in the future.

Poisoning and Entrapment

Other impacts to Santa Catalina Island foxes resulting from human interaction include mortality from poisoning and entrapment (Duncan and King 2012, p. 4; King and Duncan 2015, pp. 18, 20; Vickers 2012a, p. 2; Vickers 2012b, p. 1; King and Duncan 2015, p. 18). A Santa Catalina Island fox died in 2012 from rodenticide poisoning (Duncan and King 2012, p. 4), another was euthanized because of poisoning in 2014 (King and Duncan 2015, p. 18), and a third was sickened in 2014 by insecticide poisoning (King and Duncan 2015, p. 20). Entrapment of foxes may occur in areas where development projects are ongoing. Examples include: Two foxes falling into a power line pole construction pit (CIC 2009, *http://www.catalinaconservancy.org*); one fox drowning due to entanglement in a food container (Vickers 2012a p. 2); one fox death from being trapped in a recycling barrel (Vickers 2012b, p. 1); and two fox deaths in 2014 from drowning in water or sediment containers (King and Duncan 2015, p. 18). Types of human-caused harm other than vehicle strikes and domestic dog attacks in urbanized areas are varied, but they do not have a population-level impact at this time or in the future. Given the low numbers of foxes affected by poisoning or entrapment and the past and current population growth, we do not expect the population effect from poisoning or entrapment to increase in the future. Therefore, at this time, the best available information indicates neither poisoning nor entrapment is resulting in significant impacts at either the population or rangewide scales, and there is no indication that poisoning or entrapment on Santa Catalina Island will increase in the future.

Fire

On the northern Channel Islands, the frequency and intensity of wildland fire is less than on the adjacent mainland, because there are fewer ignition sources on the islands, and the typical maritime fog moisture inhibits fire spread. Natural lightning-strike fires are extremely rare; only three fires between 1836 and 1986 on the Channel Islands were started by lightning (Carroll *et al.* 1993, p. 77). On the northern Channel Islands, there are far fewer human-started fires than on the mainland or on Santa Catalina Island, as there are no permanent human occupants on the northern Channel Islands. Because of this, island foxes on the northern Channel Islands have experienced few large wildland fire events. The recent removal of nonnative grazers may increase fuel loads and thus the likelihood of larger fires; however, historically consistent cool and foggy conditions will continue to limit wildland fire spread, including in the future. Additionally, NPS adheres to a policy of total suppression on the Channel Islands, due to resource concerns (Kirkpatrick 2006, entire), reducing the chance that wildland fires will become large.

Though not identified as a threat at the time of listing, Santa Catalina Island regularly experiences wildfires (CIC 2011) that could reduce food availability, alter the habitat, or directly result in the loss of individual foxes (Service 2004, p. 10347). Duncan and King's (2009, p. 384) findings indicate fire seasonality has an influence on fox survival; fires that occur when pups are young and most dependent on adults for mobility are most damaging. However, in general, the best available data indicate that neither the 2006 Empire Fire nor the 2007 Island Fire had significant effects to island fox at the population level (Duncan and King 2009, p. 384).

In summary, wildfires are infrequent on the northern Channel Islands and more frequent on Santa Catalina Island. On all islands, while wildfire can result in mortality of individuals, especially juveniles depending on when the fires occur, the best available data indicate that wildfire does not pose significant impacts to the island fox at either the population or rangewide scales currently. In addition, there is no indication that fire frequency will increase in the future on the northern Channel Islands. On Santa Catalina Island, even given an increase in fire frequency since 1999, the island fox population has continued to increase (CIC 2016, *http://www.catalinaconservancy.org*). Therefore, we do not anticipate wildfire posing a significant population-level impact in the future.

Drought

The Channel Islands, as well as the rest of southern California, are currently in the midst of a drought that began in 2012, and, as of mid-April 2016, has not abated (United States Drought Monitor 2016, entire). Island foxes have endured many droughts during their 10,000-year persistence on the islands (California Department of Water Resources 2015, entire). Deep multi-year droughts have occurred on the Channel Islands about once every 2 decades since 1900 (Coonan 2015, unpubl. data). General drought conditions in the late 1920s and early 1930s, combined with overgrazing, denuded most vegetation, particularly on San Miguel Island, creating massive sand barrens, remnants of which are still evident today (Johnson 1980, entire). Even so, island foxes survived this period of soil erosion and episodic landscape stripping.

The current drought is the first opportunity to study the effect of drought on island foxes, since foxes have recovered to historic numbers. On San Miguel Island, average adult weights declined in 2013 and 2014, to the lowest ever recorded, and fox reproduction was negligible in 2013 and 2014 (Coonan *et al.* 2014, p. 28; Coonan 2015b, p. 7; Coonan 2015, unpubl. data). During this time, mortality also increased, and many fox carcasses were emaciated (Coonan 2014, pp. 6–7). However, San Miguel Island fox numbers have remained at or above pre-decline levels (Friends of the Island Fox 2015, p. 3). On Santa Catalina Island, data indicate that decreasing precipitation may result in a reproductive decline; however, adults' weights were not similarly affected during this time (King and Duncan 2015, pp. 21–22). These effects were not seen on neighboring Santa Rosa Island, where foxes are not yet at carrying capacity or pre-decline levels. Fox weights increased on Santa Rosa Island in the drought years, reproduction was higher, and foxes had higher body condition scores than on San Miguel Island (Coonan 2015b, pp. 7–8). It is apparent that one response of island foxes to drought is to curtail reproduction, especially if the population is at carrying capacity (Coonan *et al.* 2010, p. 28; Coonan 2015a, pp. 6, 13). Given the past demonstrated ability of island foxes to survive pervasive drought, current healthy population numbers, and apparent ability to respond to drought by shifting resource allocation, we do not consider drought to be a threat to island foxes at this time or in the future.

Global Climate Change

Our analyses under the Act include consideration of ongoing and projected changes in climate. Scientific measurements spanning several decades demonstrate that changes in climate are occurring, and that the rate of change has increased since the 1950s. Examples include warming of the global climate system, and substantial increases in precipitation in some regions of the world and decreases in other regions (*e.g.,* Solomon *et al.* 2007, pp. 35–54, 82–85; IPCC 2013b, pp. 3–29; IPCC 2014, pp. 1–32). Results of scientific analyses presented by the Intergovernmental Panel on Climate Change (IPCC) show that most of the observed increase in global average temperature since the mid-20th century cannot be explained by natural variability in climate and is "very likely" (defined by the IPCC as 90 percent or higher probability) due to the observed increase in greenhouse gas (GHG) concentrations in the atmosphere as a result of human activities, particularly carbon dioxide emissions from use of fossil fuels (Solomon *et al.* 2007, pp. 21–35; IPCC 2013b, pp. 11–12 and figures SPM.4 and SPM.5). Further confirmation of the role of GHGs comes from analyses by Huber and Knutti (2011, p. 4), who concluded it is extremely likely that approximately 75 percent of global warming since 1950 has been caused by human activities.

Various changes in climate may have direct or indirect effects on species. These effects may be positive, neutral, or negative, and they may change over time, depending on the species and other relevant considerations, such as threats in combination and interactions of climate with other variables (for example, habitat fragmentation) (IPCC 2014, pp. 4–11). Identifying likely effects often involves aspects of climate change vulnerability analysis. Vulnerability refers to the degree to which a species (or system) is susceptible to, and unable to cope with, adverse effects of climate change, including climate variability and extremes. Vulnerability is a function of the type, magnitude, and rate of climate change and variation to which a species is exposed, its sensitivity, and its adaptive capacity (Glick *et al.* 2011, pp. 19–22; IPCC 2014, p. 5). There is no single method for conducting such analyses that applies to all situations (Glick *et al.* 2011, p. 3). We use our expert judgment and appropriate analytical approaches to weigh relevant information, including uncertainty, in our consideration of the best scientific information available regarding various aspects of climate change.

Statewide and regional probabilistic estimates of temperature and precipitation changes for California and the greater Los Angeles region were evaluated by Pierce *et al.* (2013, entire) and Sun *et al.* (2015, entire) using dynamic downscaled simulations. Pierce *et al.* (2013, p. 854) found that, averaging across all models and downscaling methods, the warmest Julys are likely to be far warmer than historical temperatures for California. Projections for changes in precipitation by the 2060s were less certain; they showed weak overall annual mean decreases in precipitation in the southern part of the State, but with an increase in summer rain (Pierce *et al.* 2013, p. 855). Sun *et al.* (2015, p. 4,625) found that temperatures in the greater Los Angeles region for two future time periods, midcentury (2041–60) and end of century (2081–2100), will almost certainly be outside the interannual variability range seen in the baseline (1981–2000), particularly during the summer and fall. However, in each scenario and time period, the coastal areas warm less than inland areas due to generally lower warming over the ocean and the land-sea breeze circulation, which introduces a marine influence in the coastal zone (Sun *et al.* 2015, pp. 4,621–4,622). This suggests that the Channel Islands, along with the mainland's highest elevations and a narrow swath near the coast, may be somewhat buffered from the more extreme effects of a warming climate.

Probably the most potentially vulnerable aspect of island fox biology to climate change is indirect effects from affected invertebrates that are parasites and disease vectors. Invertebrates, because they are exothermic (cold-blooded), are particularly responsive to the effects of a warming climate that typically speeds development and enhances survival. For disease vectors such as mosquitos, survival may occur where it was previously too cold during the coolest nights of the year for overwintering. Invertebrates are also particularly well-suited to adapt to a changing climate because they have short generation times and a high reproductive output (Parmesan 2006, pp. 654–656). The warming climate typically has resulted in increased abundance and expanded ranges of parasites such as nematodes and ticks, as well as diseases they transmit (Parmesan 2006, pp. 650–651; Studer *et al.* 2010, p. 11). Climate change also produces ecological perturbations that result in altered parasite transmission dynamics, increasing the potential for host switching (Brooks and Hoberg 2007, p. 571). Moller's (2010, p. 1,158) analysis of parasites on avian hosts over a 37-year period suggests climate change predictions for parasite effects should be made with caution, but that climate can alter the composition of the parasite community and may cause changes in the virulence of parasites (Moller 2010, p. 1,158). Climate change may change and could potentially increase the parasites and disease vectors to which island foxes are exposed. However, we anticipate ongoing monitoring and management will detect any increase or changes in parasites or disease vectors that affect the population health of island foxes.

Considering that island foxes are opportunistic feeders, and climate warming could increase the subspecies' insect prey base abundance, it is possible climate change could positively affect food quantity and quality. For example, increased consumption of insect species by mice associated with a warmer, drier climate on South African islands has been documented (Chown and Smith 1993, pp. 508–509). In addition, because island foxes have shown relative plasticity with regard to utilizing nonnative insects (Cypher *et al.* 2011, p. 13), most invasions of nonnative potential prey species are not likely to negatively affect island fox food resources. The only potential negative effect of climate change on the insect prey base of island foxes would be if increased storm intensity and frequency reduced prey abundance, as Roemer (1999, p. 187) hypothesized occurred on Santa Cruz Island in the mid-1990s.

Global climate change has the potential to negatively and positively affect island fox populations. There is still uncertainty associated with predictions relative to the timing, location, and magnitude of future climate changes. Probably the most vulnerable aspect of island fox biology to climate change is indirect effects to the fox from affected invertebrates. Given the indications that the Channel Islands may be somewhat buffered from the more extreme effects of a warming climate and past demonstrated ability of island foxes to survive pervasive drought, current healthy population numbers, and the apparent ability of foxes to respond to changes in precipitation by shifting resource allocation, we do not consider changes in temperature or precipitation projected due to climate change to be a threat to island foxes at this time or in the future. While we cannot accurately predict the effects of climate change on island fox subspecies, because the foxes are generalists and exhibit plasticity with regards to prey and habitat use, we do not expect negative effects of such magnitude that would result in significant impacts at either the population or rangewide scales (*e.g.,* cause major declines). We anticipate ongoing monitoring and management will detect any significant changes in population health and allow for management responses, including possible relisting.

Summary of Factor E

In summary, during the period when populations were at their lowest, the four subspecies of Channel Island foxes were extremely vulnerable to extinction from stochastic events. The populations have now increased substantially and the likelihood of extinction has accordingly been reduced. The combined effects of interactions with feral cats and domestic dogs, motor vehicle collisions, mortality due to wildfire, and other human-caused mortalities result in the deaths of multiple individuals throughout Santa Catalina Island on an annual basis, but they do not constitute a combined threat to the relatively large population at this time nor do we anticipate that they will in the future. Given the past demonstrated ability of island foxes to survive pervasive drought, their current healthy population numbers, and their apparent ability to respond to drought by shifting resource allocation, we do not consider drought to be a threat to island foxes at this time or in the future. While we cannot accurately predict the effects of climate change on island fox subspecies because the foxes are generalists and exhibit plasticity with regards to prey, habitat use, and resource allocation, we do not consider climate change to be a threat to island foxes now nor in the future.

Overall Summary of Factors Affecting Island Foxes

At time of listing in 2004 (69 FR 10335; March 5, 2004), predation by golden eagles was the primary threat to San Miguel, Santa Rosa, and Santa Cruz Island foxes, and disease was the primary threat to the Santa Catalina Island fox. The threat of predation by golden eagles on the northern Channel Islands has been significantly reduced since the time of listing. This reduction in predation by golden eagles is in direct response to the extensive removal of golden eagles from the northern Channel Islands, golden eagle prey being removed successfully from Santa Rosa and Santa Cruz Islands, and the successful reintroduction of bald eagles.

Potential disease outbreaks continue to pose a threat to Santa Catalina Island foxes due to relatively uncontrolled movement of vectors from the mainland that carry diseases for which the population may not be vaccinated. The primary measures in place on all islands to reduce the threat of disease are vaccination of a subset of the fox population for CDV and rabies, and monitoring of population sentinels to detect the start of another epidemic and respond appropriately to mitigate the outbreak. While disease is currently controlled on Santa Catalina Island, we do not have assurance that monitoring and management of Santa Catalina Island foxes necessary to detect and mitigate an epidemic in Santa Catalina Island foxes will continue in the future.

During the period when the island fox populations were at their lowest, they were extremely vulnerable to extinction from stochastic events. There will always be some inherent risk of extinction due to stochastic events because each island fox subspecies is a single breeding population. However, the populations have now increased substantially, show stable or increasing trends, and are returning to historical population levels, and the threat of extinction from demographic stochasticity has accordingly been reduced.

Mortality due to motor vehicle strikes, habitat loss, feral cats, and domestic dogs results in loss of individuals, but these mortality factors are not resulting in significant impacts to island foxes at either the population or rangewide scales as documented by current population numbers and trends. When population numbers are healthy, island foxes respond to drought by shifting resource allocation; therefore, we do not consider drought to be a threat to island foxes at this time or in the future. The impacts of climate change are hard to predict. Some effects to island fox populations could be negative while others could be positive. Predicting likely future climate scenarios and understanding the complex effects of climate change are high priorities for island fox conservation planning.

Climate change is not considered a threat now or in the future because of the past demonstrated ability of island foxes to survive pervasive drought, their current healthy population numbers, the indication that the Channel Islands may be somewhat buffered from the more extreme effects of a warming climate, and the apparent ability of foxes to respond to changes in precipitation by shifting resource allocation.

When mortality mechanisms or other stressors occur together, one may exacerbate the effects of another, causing effects not accounted for when stressors are analyzed individually. Synergistic or cumulative effects may be observed in a short amount of time or may not be noticeable for years into the future, and could affect the long-term viability of island fox populations. For example, if a stressor hinders island fox survival and reproduction or affects the availability of habitat that supports island foxes, then the number of individuals the following year(s) will be reduced, increasing vulnerability to stochastic events like a disease epidemic or wildfire. The combined effects of interactions with feral cats and domestic dogs, motor vehicle collisions, mortality due to wildfire, and other human-caused mortalities result in the deaths of multiple individuals throughout Santa Catalina Island on an annual basis, but they do not constitute a combined threat to the relatively large population at this time nor do we anticipate that they will in the future. Another example is San Miguel Island where there have been combined effects of low reproductive output, dry climate, parasites, and low genetic variability. However, population estimates for the total San Miguel Island fox population likely represents carrying capacity for the island (Coonan 2014, p. 8), which has resulted in a general decline in reproductive effort as the population has increased. In addition, according to population viability analyses the San Miguel Island fox subspecies is at acceptably low risk of extinction (Guglielmino and Coonan 2016, p. 17) indicating that low reproductive output, dry climate, parasites, and low genetic variability do not constitute a combined threat to the population at this time nor do we anticipate that they will in the future. In conducting this analysis, we have considered whether the individual stressors identified for each island, considered in combination, result in a threat to the species. The combination of low mortality and robust population growth puts each island fox subspecies at acceptably low risk of extinction, according to population viability analyses. While synergistic or cumulative effects may occur when mortality mechanisms or other stressors occur together, given the robust populations and ongoing management and monitoring, these effects do not pose significant impacts to San Miguel, Santa Rosa, and Santa Cruz Island foxes at either the population or rangewide scales at this time nor do we anticipate that they will in the future. Synergistic or cumulative effects do not pose significant impacts to Santa Catalina Island fox at either the population or rangewide scales at this time given the robust populations and current ongoing management and monitoring, but could in the future if there are lapses in monitoring and management in the future.

Determination

An assessment of the need for a species' protection under the Act is based on whether a species is in danger of extinction or likely to become so because of any of five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or human-made factors affecting its continued existence. As required by section 4(a)(1) of the Act, we conducted a review of the status of these species and assessed the five factors to evaluate whether the San Miguel, Santa Rosa, Santa Cruz, and Santa Catalina Island foxes are in danger of extinction, or likely to become so in the foreseeable future throughout all or a significant portion of their ranges. We examined the best scientific and commercial information available regarding the past, present, and future threats faced by these subspecies. We also consulted with species experts and land management staff with NPS, TNC, and CIC, who are actively managing for the conservation of island foxes.

In considering what factors might constitute threats, we must look beyond the mere exposure of the species to the factor to determine whether the exposure causes actual impacts to the species. If there is exposure to a factor, but no response, or only a positive response, that factor is not a threat. If there is exposure and the species responds negatively, the factor may be a threat and we then attempt to determine how significant the threat is. If the threat is significant, it may drive, or contribute to, the risk of extinction of the species such that the species warrants listing as an endangered species or threatened species as those terms are defined by the Act. This determination does not necessarily require empirical proof of a threat. The combination of exposure and some corroborating evidence of how the species is likely impacted could suffice. The mere identification of factors that could impact a species negatively is not sufficient to compel a finding that listing is appropriate; we require evidence that these factors are operative threats that act on the species to the point that the species meets the definition of an endangered species or threatened species under the Act.

At the time of listing in 2004 (69 FR 10335; March 5, 2004), the Santa Catalina Island fox experienced a devastating CDV epidemic that resulted in an almost complete loss of the eastern subpopulation, which made up the majority of the island population. The precipitous decline of the northern Channel Island foxes (San Miguel, Santa Rosa, and Santa Cruz Island foxes) that led to their listing as endangered species was the result of depredation by golden eagles, facilitated by the presence of a nonnative, mammalian prey-base on the northern Channel Islands.

As a result of concerted management efforts, golden eagle predation has been reduced to such a degree that it is no longer considered a threat to the northern island subspecies. Additional management efforts, including captive breeding and ongoing vaccinations for disease, have contributed to the substantial increase of all island fox populations. Although golden eagles will most likely continue to occasionally occur on the islands as transients, the removal of the nonnative prey-base and the constant presence of bald eagles are permanent, long-term deterrents to golden eagles establishing breeding territories and remaining on the northern Channel Islands. Ongoing management and monitoring are designed to detect any reemergence of threats and to take corrective actions should any threats be detected.

Northern Channel Islands Subspecies

Based on the information presented in this final rule and the proposed rule (81 FR 7723; February 16, 2016), the recovery criteria in the recovery plan have been achieved and the recovery objectives identified in the recovery plan have been met for the three northern Channel Island subspecies of island fox. San Miguel, Santa Rosa, and Santa Cruz Island fox abundance has increased steadily to the point where the number of individuals is again within the range of historical population estimates, save Santa Rosa Island where numbers are returning to historical population levels. Population viability analyses strongly indicate that the northern Channel Island foxes have an acceptably small risk of extinction and current population levels are consistent with long-term viability. Additionally, the primary threat (golden eagles) to northern Channel Island foxes has been controlled, and ongoing management and monitoring are in place to ensure that threats continue to be managed in the future. This information indicates that these three subspecies are no longer at immediate risk of extinction, nor are they likely to experience reemergence of threats and associated population declines in the future. We, therefore, conclude that the San Miguel, Santa Rosa, and Santa Cruz Island foxes are no longer experiencing significant impacts at either the population or rangewide scales. Thus, these island fox subspecies are no longer in danger of extinction throughout all of their ranges, nor are they likely to become so within the foreseeable future.

Significant Portion of the Range

Having determined that the San Miguel, Santa Rosa, and Santa Cruz Island foxes are not in danger of extinction, or likely to become so, throughout all of their ranges, we next consider whether there are any significant portions of their ranges in which the island foxes are in danger of extinction or likely to become so. Under the Act and our implementing regulations, a species may warrant listing if it is an endangered species or a threatened species. The Act defines "endangered species" as any species which is "in danger of extinction throughout all or a significant portion of its range," and "threatened species" as any species which is "likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range." The term "species" includes "any subspecies of fish or wildlife or plants, and any distinct population segment [DPS] of any species of vertebrate fish or wildlife which interbreeds when mature." On July 1, 2014, we published a final policy interpreting the phrase "significant portion of its range" (SPR) (79 FR 37578). The final policy states that (1) if a species is found to be endangered or threatened throughout a significant portion of its range, the entire species is listed as an endangered species or a threatened species, respectively, and the Act's protections apply to all individuals of the species wherever found; (2) a portion of the range of a species is "significant" if the species is not currently endangered or threatened throughout all of its range, but the portion's contribution to the viability of the species is so important that, without the members in that portion, the species would be in danger of extinction, or likely to become so in the foreseeable future, throughout all of its range; (3) the range of a species is considered to be the general geographical area within which that species can be found at the time the Service or the National Marine Fisheries Service makes any particular status determination; and (4) if a vertebrate species is endangered or threatened throughout an SPR, and the population in that significant portion is a valid DPS, we will list the DPS rather than the entire taxonomic species or subspecies.

The SPR policy is applied to all status determinations, including analyses for the purposes of making listing, delisting, and reclassification determinations. The procedure for analyzing whether any portion is an SPR is similar, regardless of the type of status determination we are making. The first step in our analysis of the status of a species is to determine its status throughout all of its range. If we determine that the species is in danger of extinction, or likely to become so in the foreseeable future, throughout all of its range, we list the species as an endangered (or threatened) species and no SPR analysis will be required. Because we are reclassifying the listing status of the Santa Catalina Island fox as a threatened species under the Act (see *Santa Catalina Island Fox,* below), we are not conducting an SPR analysis for this subspecies. If the species is neither endangered nor threatened throughout all of its range, we determine whether the species is endangered or threatened throughout a significant portion of its range. If it is, we list the species as an endangered species or a threatened species, respectively; if it is not, we conclude that the species is neither an endangered species nor a threatened species.

When we conduct an SPR analysis, we first identify any portions of the species' range that warrant further consideration. The range of a species can theoretically be divided into portions in an infinite number of ways. However, there is no purpose to analyzing portions of the range that are not reasonably likely to be significant and either endangered or threatened. To identify only those portions that warrant further consideration, we determine whether there is substantial information indicating that (1) the portions may be significant and (2) the species may be in danger of extinction in those portions or likely to become so within the foreseeable future. We emphasize that answering these questions in the affirmative is not a determination that the species is endangered or threatened throughout a significant portion of its range—rather, it is a step in determining whether a more detailed analysis of the issue is required. In practice, a key part of this analysis is whether the threats are geographically concentrated in some way. If the threats to the species are affecting it uniformly throughout its range, no portion is likely to warrant further consideration. Moreover, if any concentration of threats apply only to portions of the range that clearly do not meet the biologically based definition of "significant" (*i.e.,* the loss of that portion clearly would not be expected to increase the vulnerability to extinction of the entire species), those portions will not warrant further consideration.

If we identify any portions that may be both (1) significant and (2) endangered or threatened, we engage in a more detailed analysis. As discussed above, to determine whether a portion of the range of a species is significant, we consider whether, under a hypothetical scenario, the portion's contribution to the viability of the species is so important that, without the members in that portion, the species would be in danger of extinction or likely to become so in the foreseeable future throughout all of its range. This analysis considers the contribution of that portion to the viability of the species based on the conservation biology principles of redundancy, resiliency, and representation. (These concepts can similarly be expressed in terms of abundance, spatial distribution, productivity, and diversity.) The identification of an SPR does not create a presumption, prejudgment, or other determination as to whether the species in that identified SPR is in danger of extinction or likely to become so. We must go through a separate analysis to determine whether the species is in danger of extinction or likely to become so in the SPR. To determine whether a species is endangered or threatened throughout an SPR, we will use the same standards and methodology that we use to determine if a species is endangered or threatened throughout its range.

Depending on the biology of the species, its range, and the threats it faces, it may be more efficient to address either the significance question first, or the status question first. Thus, if we determine that a portion of the range is not "significant," we do not need to determine whether the species is endangered or threatened there; if we determine that the species is not endangered or threatened in a portion of its range, we do not need to determine if that portion is "significant."

Applying the process described above, we evaluated the respective ranges of the San Miguel Island fox, Santa Rosa Island fox, and Santa Cruz Island fox to determine if any area could be considered a significant portion of any one of the subspecies' ranges. As mentioned above, one way to identify portions for further analyses is to identify areas that may be significant, such as any natural divisions within the range that might be of individual biological or conservation importance to the species. We conducted our review based on examination of the recovery plan (Service 2015; entire) and other relevant and more recent information on the biology and life history of the northern Channel Island foxes. Because each of the three northern Channel Island fox subspecies is a narrow endemic where the foxes on each island constitute a single population, we determined that there are no natural divisions or separate areas of the range of each subspecies that contribute separately to the conservation of that particular subspecies. In other words, for each subspecies of island fox, there is only one biologically defined portion, and there are no notably separate or distinct portions that contribute independently to the conservation (*i.e.*, to the redundancy, resiliency, and representation) of the species. We also examined whether any portions might be endangered or threatened by examining whether threats might be geographically concentrated in some way. Although some of the factors we evaluated under Summary of Factors Affecting the Species, above, may continue to affect each of the subspecies, the factors affecting island foxes generally occur at similarly low levels throughout each of their ranges. The entire population of each subspecies is equally affected by threats and by the amelioration of such threats throughout their ranges. Based on our evaluation of the biology of the subspecies and current and potential threats to the island foxes, we conclude that no portion of the ranges of the three subspecies of the northern Channel Islands foxes warrants further consideration to determine if it is significant. In other words, threats have been sufficiently ameliorated, and all individuals and all portions of the range of each subspecies interact to such an extent that it is not reasonable to conclude that any portion of the range can have a different status than any other portion.

We have carefully assessed the best scientific and commercial data available and determined that the San Miguel Island fox, Santa Rosa Island fox, and Santa Cruz Island fox are no longer in danger of extinction throughout all or significant portions of their ranges, nor are they likely to become so within the foreseeable future. As a consequence of this determination, we are removing the San Miguel, Santa Rosa, and Santa Cruz Island fox from the Federal List of Endangered and Threatened Wildlife.

Santa Catalina Island Fox

The Santa Catalina Island fox exhibits demographic characteristics consistent with long-term viability. The population has continued to increase over the past 11 years, reaching an estimated high of 1,852 individuals in 2013 (King and Duncan 2015, p. 11), then dropping slightly to 1,812 in 2015 (King and Duncan 2016, p. 10). Population viability analysis indicates the Santa Catalina Island fox population has an acceptably small risk of extinction—less than 5 percent since 2008. With population levels consistent with long-term viability, the intent of recovery objective 1 has been met for the Santa Catalina Island fox. However, objective 2 has not been met because we do not have assurance that the monitoring and management as prescribed in the epidemic response plan for Santa Catalina Island foxes will be funded and implemented in the future to ensure that the threat of disease continues to be managed. While population levels are currently consistent with long-term viability (indicating that the subspecies is no longer currently in danger of extinction), lack of adequate control of potential vectors along with lack of assured long-term monitoring could allow for lapses in management and monitoring and reemergence of disease that may cause epidemics and population declines before they can be detected and acted upon. We coordinated with CIC to determine their ability to enter into an agreement to provide assurances for long-term funding and a commitment for long-term implementation of the epidemic response plan. Though we do not have assurances of long-term funding that would allow them to commit to long-term implementation of the epidemic response plan, we recognize that CIC's efforts have significantly contributed to a reduction of impacts to the Santa Catalina Island fox and its habitat. As a result, we have determined that the Santa Catalina Island fox is no longer in danger of extinction throughout all of its range, but instead is threatened with becoming endangered in the foreseeable future throughout all of its range. Therefore, we are reclassifying the status of the Santa Catalina Island fox from an endangered species to a threatened species. Because we have determined the Santa Catalina Island fox is likely to become an endangered species in the foreseeable future throughout all of its range, no portion of its range can be significant for purposes of the definitions of endangered species or threatened species (see 79 FR 37578; July 1, 2014) (also see Significant Portion of the Range, above).

Critical Habitat

Section 4(a)(3)(A) of the Act, as amended, and implementing regulations (50 CFR 424.12) require that we designate critical habitat, to the maximum extent prudent and determinable, at the time a species is listed as endangered or threatened.

On November 9, 2005 (70 FR 67924), we determined that habitat on Santa Catalina Island (as well as the other three islands occupied by the island fox described herein) did not meet the definition of critical habitat under the Act. We made this determination based on the island fox being a generalist in all aspects of its life history. We stated that foxes are opportunistic omnivores that eat a wide variety of plants and animals in whatever habitat they use, and as such, they use all habitat available on each of the islands (70 FR 67927). We were not aware at that time nor are we aware currently of any existing or anticipated threats to Santa Catalina Island habitats that would likely affect the Santa Catalina Island fox. Accordingly, we continue to conclude that there is no information to support a conclusion that any specific habitat on Santa Catalina Island is essential to the conservation of the Santa Catalina Island fox. Thus, we do not find any habitat on Santa Catalina Island that meets the definition of critical habitat in section 3(5)(A) of the Act. Because there continues to be no habitat that meets the definition of critical habitat for the Santa Catalina Island fox, there is none to designate.

Effects of This Rule

This final rule revises 50 CFR 17.11(h) by removing the San Miguel Island fox, Santa Rosa Island fox, and Santa Cruz Island fox from the Federal List of Endangered and Threatened Wildlife. The prohibitions and conservation measures provided by the Act, particularly through sections 7 and 9, no longer apply to these subspecies. Federal agencies are no longer required to consult with the Service under section 7 of the Act in to ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of these subspecies.

This rule also revises 50 CFR 17.11(h) to reclassify the Santa Catalina Island fox from an endangered species to a threatened species on the Federal List of Endangered and Threatened Wildlife. However, this reclassification does not change the protection afforded to this subspecies under the Act. Anyone taking, attempting to take, or otherwise possessing this species, or parts thereof, in violation of section 9 of the Act or its implementing regulations, is subject to a penalty under section 11 of the Act. Pursuant to section 7 of the Act, Federal agencies must ensure that any actions they authorize, fund, or carry out are not likely to jeopardize the continued existence of the Santa Catalina Island fox. Whenever a species is listed as threatened, the Act allows promulgation of special rules under section 4(d) that modify the standard protections for threatened species found under section 9 of the Act and Service regulations at 50 CFR 17.31 (for wildlife) and 17.71 (for plants), when it is deemed necessary and advisable to provide for the conservation of the species. No special section 4(d) rules are proposed, or anticipated to be proposed, for Santa Catalina Island fox, because there is currently no conservation need to do so for this subspecies. Recovery actions directed at Santa Catalina Island fox will continue to be implemented, as funding allows, as outlined in the recovery plan for this species (Service 2015, entire).

Future Conservation Measures

Section 4(g)(1) of the Act requires us, in cooperation with the States, to implement a monitoring program for not less than 5 years for all species that have been recovered and delisted. The purpose of this post-delisting monitoring (PDM) is to verify that a species remains secure from risk of extinction after the protections of the Act are removed, by developing a program that detects the failure of any delisted species to sustain itself. If, at any time during the monitoring period, data indicate that protective status under the Act should be reinstated, we can initiate listing procedures, including, if appropriate, emergency listing under section 4(b)(7) of the Act.

Post-Delisting Monitoring Plan

NPS and TNC have agreed to partner with us in the implementation of the post-delisting monitoring for the northern Channel Island foxes. The post-delisting monitoring is designed to verify that San Miguel, Santa Rosa, and Santa Cruz Island foxes remain secure from risk of extinction after their removal from the Federal List of Endangered and Threatened Wildlife by detecting changes in population trend and mortality/survival. Post-delisting monitoring for the northern Channel Island fox subspecies will be conducted as recommended in the epidemic response plan for northern Channel Island foxes (Hudgens *et al.* 2013, entire) and golden eagle management strategy (NPS 2015a, entire). These documents are available on the Internet at *https://www.regulations.gov* at Docket No. FWS–R8–ES–2015–0170, and the Ventura Fish and Wildlife Office's Web site at *http://www.fws.gov/Ventura/.*

Although the Act has a minimum post-delisting monitoring requirement of 5 years, the post-delisting monitoring plan for northern Channel Island foxes includes a 10-year monitoring period to account for environmental variability (for example, extended drought) that may affect fox populations and to document the range of population fluctuation as fox populations reach carrying capacity. If a decline in abundance is observed or a substantial new threat arises, post-delisting monitoring may be extended or modified as described below.

Island foxes will be monitored for both population size and trend, and for annual survival and cause-specific mortality, as specified by the epidemic response plan for northern Channel island foxes (Hudgens *et al.* 2013, entire) and the golden eagle management strategy (NPS 2015a, entire). Monitoring as recommended in these plans is currently being implemented. Population size and trend are estimated using capture-mark-recapture data from trapping foxes on grids (Rubin *et al.* 2007, p. 2–1; Coonan 2014, p. 2). Such monitoring has been implemented for island foxes since the late 1980s. The monitoring provides a continuous record of population fluctuation, including decline and recovery, upon which population viability analysis was used to develop island fox demographic recovery objectives (Bakker and Doak 2009, entire; Bakker *et al.* 2009, entire).

Annual survival and cause-specific mortality of island foxes will be monitored, as they are now, via tracking of radio-collared foxes. Mortality checks will be conducted weekly on radio-collared foxes, and necropsies will be conducted on fox carcasses to determine the cause of mortality. A sample of at least 40 radio-collared foxes is maintained on each island, as that is the number of monitored foxes determined to be necessary to detect an annual predation rate of 2.5 percent (Rubin *et al.* 2007, p. 2–20). This level of radio-telemetry monitoring is part of the epidemic response plan and the golden eagle management strategy for island foxes on the northern Channel Islands (Hudgens *et al.* 2013, pp. 7–11).

In cooperation with NPS and TNC, we will annually review the results of monitoring, which include annual estimated adult population size, annual adult survival, and identified causes of mortality. If there are apparent sharp declines in population size or survival, or if the information indicates the appearance of significant mortality causes, the data will be reviewed by the Island Fox Conservation Working Group for evaluation and assessment of threat level. Monitoring results may also reach thresholds which precipitate increased monitoring or implementation of management actions, as specified in the epidemic response plan and golden eagle management strategy. At the end of the 10-year post-delisting monitoring period, NPS, TNC, and the Service will determine whether monitoring should continue beyond the 10-year monitoring period.

Summary of Comments and Recommendations

In the proposed rule published on February 16, 2016 (81 FR 7723) in the **Federal Register**, we requested that all interested parties submit written comments on the proposal by April 18, 2016. We also contacted appropriate Federal and State agencies, Tribal entities, scientific experts and organizations, and other interested parties and invited them to comment on the proposal. We did not receive any requests for a public hearing. All substantive information provided during comment periods has either been incorporated directly into this final determination or is addressed below.

Peer Reviewer Comments

In accordance with our peer review policy published on July 1, 1994 (59 FR 34270), we solicited expert opinion from three knowledgeable individuals with scientific expertise that included familiarity with the island fox and its habitat, biological needs, and threats. We received responses from all three of the peer reviewers.

We reviewed all comments we received from the peer reviewers for substantive issues and new information regarding the status of the island fox. The peer reviewers generally concurred with our methods and conclusions, and provided new information and suggestions to improve the final rule. This information has been incorporated into the final rule as appropriate. The peer reviewer comments are addressed in the following summary.

Comments From Peer Reviewers

(1) Comment: Two peer reviewers requested further mention of lack of genetic diversity as an important consideration for island foxes. They stated that numerous studies have now shown that island fox populations lack genetic variation, an outcome of long-term small population sizes and bottlenecks, coupled with the pervasive effects of genetic drift. The peer reviewers stated that although the threats to island fox populations on the northern Channel Islands have either been reduced or addressed and the populations have recovered to approximately historic levels, the various subspecies lack genetic variation, which could compromise their ability to respond to future environmental change if managers do not respond to a potential decline in a timely manner.

Our Response: We included the relevant scientific information presented by the peer reviewers related to lack of genetic variation in this final rule. We anticipate that ongoing monitoring and management as described in signed CMAs with NPS and TNC (Service and NPS 2015; Service and TNC 2015) will detect any significant changes in population health and allow for management responses, including possible relisting. If a decline is detected, we will act in concert with NPS and TNC in an expedient manner to uncover the agent of the decline and implement timely recovery actions as laid out in the golden eagle management strategy and epidemic response plans (Hudgens *et al.* 2013, entire; NPS 2015a, entire).

(2) Comment: One peer reviewer requested more information about evaluation of recovery objective 1 and recovery criteria E/1. In particular, the peer reviewer asked if demographic characteristics included measures of genetic characteristics, as the same standards should not apply to populations that have lost much of their genetic variation.

Our Response: Recovery objective 1 is that each federally listed subspecies of island fox exhibits demographic characteristics consistent with long-term viability. Recovery objective 1 is achieved when recovery criteria E/1 is met: an island fox subspecies has no more than 5 percent risk of quasi-extinction over a 50-year period; recovery criteria E/1 has been met. Recovery criteria E/1 is evaluated for each species using population viability models presented in Bakker *et al.* (2009) and appendix 2 of the recovery plan (Service 2015, pp. 135–140) that incorporate demographic information for each subspecies of island fox, which are influenced by genetics and the environment. Genetic variation is not one of the demographic characters that is measured, although we recognize that genetic variation has an influence on demographic characters.

(3) Comment: One peer reviewer asked how the quasi-extinction number of 30 individuals was derived. The peer reviewer asserted that if extreme bottleneck events have occurred, it is highly possible that quasi-extinction levels of 30 individuals are not appropriate, and numbers this low could essentially extirpate any genetic variation left in the population.

Our Response: Because short- to medium-term risk analysis is most important for island fox management, Bakker *et al.* (2009) ran each simulation for 50 years and used a quasi-extinction threshold of 30 foxes, set by the Service's island fox Recovery Team to further account for unidentified biological and sociopolitical uncertainties (Bakker *et al.* 2009, p. 92). We concur with the quasi-extinction level determined by the scientists on the island fox Recovery Team. However, we note that monitoring and management is designed to intervene well before a species would reach a quasi-extinction threshold. Quasi-extinction is not the threshold for action; rather, triggers for action would be if monitoring results indicate a sharp decline in population size or survival or the appearance of a significant mortality source. The intent is to avoid the quasi-extinction threshold by a wide margin by managing for a low risk of reaching such a threshold over a fairly long period of time.

(4) Comment: One peer reviewer asked what it would take to delist the Santa Catalina Island subspecies.

Our Response: The best available scientific data for Santa Catalina Island suggest that while Santa Catalina Island fox populations have increased to self-sustaining levels, potential disease epidemic remains an ongoing threat. Once disease and disease risk are controlled and managed to the point they are no longer a threat to the subspecies, and assuming no other stressors are resulting in significant impacts at either the population or rangewide scales, the Santa Catalina Island fox could be removed from the Federal List of Endangered and Threatened Wildlife (that is, delisted). Controlling the threat of disease would include assurances of long-term implementation of the epidemic response plan for Santa Catalina Island, which is currently being implemented by CIC. We coordinated with CIC to determine their ability to enter into an agreement to provide assurances, and they indicated they are currently unable to provide assurances for long-term funding and management. Though we do not have assurances of long-term funding that would allow them to commit to long-term implementation of the epidemic response plan, we recognize that CIC's efforts have significantly contributed to a reduction of impacts to the Santa Catalina Island fox and its habitat.

Public Comments

We requested written comments from the public on the proposed rule. To that end, we specifically sought comments concerning: (1) Additional information on the distribution, population size, and population trends of the San Miguel, Santa Rosa, Santa Cruz, and Santa Catalina Island foxes; (2) relevant information concerning any current or likely future threats (or lack thereof) to the island foxes; (3) current or planned activities within the range of the island foxes and their possible impacts; (4) regional climate change models and whether they are reliable and credible to use in assessing the effects of climate change on the island foxes and their habitats; and (5) our draft post-delisting monitoring plan.

During the open comment period, which closed on April 18, 2016, we received 10 comment letters from organizations or individuals directly addressing the proposed removal of the San Miguel, Santa Rosa, and Santa Cruz Island fox from the Federal List of Endangered and Threatened Wildlife, or reclassification of the Santa Catalina Island fox from an endangered to a threatened species. Seven of these letters opposed the proposal, and three provided support. Two of these letters provided substantive comments (beyond a succinct expression of agreement or opposition) on the proposed rule, one of which supported and one of which opposed our proposal. Substantive information has been incorporated into the final rule as appropriate. The public comments are addressed in the following summary.

Comments From the Public

(5) Comment: One commenter suggested we conduct a more detailed analysis of the effects of global climate change and that we hold public meetings to develop a response plan for climate change.

Our Response: We incorporated additional information into the climate change discussion in this rule based on new information that was provided by the peer reviewers. While we cannot accurately predict the effects of climate change on island fox subspecies, because the foxes are generalists and exhibit plasticity with regards to prey and habitat use, we do not expect negative effects of such magnitude that would result in significant impacts at either the population or rangewide scales (*e.g.*, cause major population declines). However, we anticipate ongoing monitoring and management will detect any significant changes in population health and allow for management responses, including possible relisting; therefore, public meetings to develop a response plan were not planned.

(6) Comment: One commenter expressed concern that if the northern Channel Islands subspecies are delisted, the disease and predator management programs may potentially be defunded.

Our Response: The post-delisting monitoring is designed to verify that northern Channel Island foxes remain secure from risk of extinction after their removal from the Federal List of Endangered and Threatened Wildlife by detecting changes in population trend and mortality/survival. Post-delisting monitoring for the northern Channel Island fox subspecies will be conducted as recommended in the epidemic response plan for northern Channel Island foxes (Hudgens *et al.* 2013, entire) and golden eagle management strategy (NPS 2015a, entire). Funding and implementation of post-delisting monitoring is assured for 10 years by signed CMAs between the Service, NPS, and TNC (Service and NPS 2015; Service and TNC 2015). At the end of the 10-year post-delisting monitoring period, the Service, NPS, and TNC will determine whether monitoring should continue beyond the 10-year monitoring period. In addition, NPS identified island foxes as an ecosystem element for which they will conduct long-term annual population monitoring as part of Channel Island National Park's long-term ecological monitoring program, regardless of their status under the Act.

(7) Comment: One commenter stated that the San Miguel Island fox population declined from 581 individuals in 2011 (Coonan and Gugliolmino 2011, p. 14) to 538 individuals in 2012 (Coonan 2013, p. 10), despite the high number of pups caught and low number of known mortalities. The commenter questioned the 2015 data presented in the proposed rule, which indicate that the San Miguel Island population rose by approximately 200 from 2014, despite less than a quarter of the number of captured pups compared to 2012 and more than triple the number of known mortalities. The commenter also pointed out that Santa Rosa Island foxes have yet to meet their carrying capacity, and so, given that population's limited size, delisting is inappropriate at this time.

Our Response: The population estimates presented in this rule for the San Miguel Island fox are based on the best available scientific information as reported to the Service by NPS. San Miguel Island fox population estimates for the total population (both adults and juveniles) reveal that the subspecies has hovered around at least 550 foxes since 2010, and this likely represents carrying capacity for that island (Coonan 2014, p. 8). This is supported by the general decline in reproductive effort as the population has increased. On the San Miguel Island monitoring grids, only three pups were caught in 2013 and 2014, and only seven were caught in 2015, compared to 32 caught in 2012 (Guglielmino and Coonan 2016, p. 13). The low reproductive output is likely due both to high fox density and extended drought. Even given this, the overall combination of low mortality and robust population growth continues to put the San Miguel Island fox subspecies at acceptably low risk of extinction, according to population viability analyses (Guglielmino and Coonan 2016, p. 17). The San Miguel population reached this level of acceptable extinction risk in 2009, and even recent mortality due to drought has not moved the population away from acceptable extinction risk.

Santa Rosa Island foxes have likely not reached carrying capacity. Carrying capacity is not a threshold for recovery or for healthy populations; rather, carrying capacity is the maximum number of individuals that the habitat can support. Most populations function below that threshold and still exhibit demographic characteristics for healthy, stable populations. Populations do not need to be at carrying capacity to have stable or increasing demographics consistent with long-term viability. On Santa Rosa Island, significant mortality during the early phase of reintroduction and again in 2010 prevented the Santa Rosa subspecies from attaining the level of biological recovery that the San Miguel and Santa Cruz Islands subspecies had attained by 2013. However, the predicted extinction risk (over the next 50 years) has been less than 5 percent since 2011 for Santa Rosa Island (Guglielmino and Coonan 2016, p. 22). As of 2015, all Roosevelt elk and mule deer have been removed from Santa Rosa Island, and the island fox population has increased to greater than 1,200 foxes (Coonan 2015b, pers. comm.; Guglielmino and Coonan 2016, p. 18). With the golden eagle management strategy in place, complete removal of golden eagles and their nonnative prey-base from the northern Channel Islands, development and implementation of an epidemic response plan, and population levels consistent with long-term viability, the intent of recovery objectives 1 and 2, and the associated recovery criteria, are met for the San Miguel, Santa Rosa, and Santa Cruz Island foxes.

(8) Comment: One commenter presented information on Acanthocephalan parasites, which affect the gut of island foxes. The commenter stated that Acanthocephalans have been identified as a factor in the deaths of over 20 island foxes since 2013. In addition, the commenter pointed out that most of the foxes on San Miguel Island have become increasingly underweight and probably infected. The commenter expressed that the effect this parasite could have on the San Miguel population of island foxes is significant and there is too little information on this significant issue to proceed with the proposed delisting.

Our Response: In 2013, necropsies of five radio-collared San Miguel Island foxes revealed substantial, and in several cases massive, parasitism by an unidentified Acanthocephalan (spiny-headed) parasite in the intestines (Coonan *et al.* 2014b, pp. 11, 12). Six of the 16 mortalities in 2014 through June 2015 had infection by an Acanthocephalan parasite, as did five in 2013 (Coonan 2015b, pp. 7, 8). The parasite burdens were associated with one or a combination of colitis, enteritis, and emaciation, and likely contributed to mortality of the individuals, but have not yet been determined as the cause of mortality (Coonan 2015b, p. 2). In 2015, the Island Fox Health Working Group discussed the impact of Acanthocephalans to island foxes on San Miguel Island and determined that no specific management action or treatment is recommended at this time, as cases are continuing, but do not appear to be increasing or causing a population decline (Coonan 2015b, p. 15). Continued monitoring of mortality causes will determine whether the parasite is a significant mortality source for San Miguel foxes, and requires management. Thus, at this time, the best available data indicate that although potential impacts from Acanthocephalan parasites may be impacting San Miguel Island fox individuals, there are no significant impacts at the population scale such that this parasite would be considered a threat to the subspecies. We anticipate that ongoing monitoring and management as described in signed CMAs with NPS and TNC (Service and NPS 2015; Service and TNC 2015) will detect any significant changes in population health and allow for management responses, including listing in the future if warranted.

(9) Comment: One commenter presented information that the San Miguel Island fox population is aging and that there are problems in reproduction or survival of pups. Information was presented by the commenter that 73 percent of the collared foxes are 4 to 10 years old, while 47 percent are 6 to 10 years old. Only 27 percent of these foxes are young animals of 1 to 3 years old, which reflects 3 consecutive years of poor recruitment for the population, signifying poor birth years or poor pup survival. The commenter stated that such an age structure puts this population at risk, particularly given the small size of the population, dry climate, parasite issue, and low genetic diversity among the San Miguel Island foxes.

Our Response: Population estimates for the total San Miguel Island fox population (both adults and juveniles) reveal that it has hovered around 550 foxes since 2010, and this likely represents carrying capacity for the island (Coonan 2014, p. 8). This is supported by the general decline in reproductive effort as the population has increased. During annual monitoring efforts, only three pups were caught in 2013 and 2014, and only seven were caught in 2015, compared to 32 caught in 2012 (Guglielmino and Coonan 2016, p. 13). The low reproductive output is likely due both to high fox density and extended drought, and is to be expected as the population hovers around carrying capacity and responds to extended drought. This does not in and of itself constitute a threat to the San Miguel Island fox population, and low reproductive effort has not been identified as a current threat to any island fox population.

The combination of low mortality and the population at likely carrying capacity (*i.e.,* 550 foxes since 2010 (Coonan 2014, p. 8)) puts the San Miguel Island fox subspecies at acceptably low risk of extinction, according to population viability analyses (Guglielmino and Coonan 2016, p. 17). We anticipate that ongoing monitoring and management as described in signed CMAs with NPS and TNC (Service and NPS 2015; Service and TNC 2015) will detect any significant changes in population health and allow for management responses, including listing in the future if warranted. If a significant decline is detected, we will act in concert with NPS and TNC in an expedient manner to uncover the agent of the decline and implement timely recovery actions as laid out in the golden eagle management strategy and epidemic response plans (Hudgens *et al.* 2013, entire; NPS 2015a, entire).

Required Determinations

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

We have determined that environmental assessments and environmental impact statements, as defined under the authority of the National Environmental Policy Act, need not be prepared in connection with listing, delisting, or reclassification of a species as an endangered or threatened species under the Endangered Species Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

References Cited

A complete list of references cited in this rulemaking is available on the Internet at *http://www.regulations.gov* under Docket No. FWS–R8–ES–2015–0170 or upon request from the Ventura Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this final rule are staff members of the Ventura Fish and Wildlife Office in Ventura, California, in coordination with the Pacific Southwest Regional Office in Sacramento, California, and the Carlsbad Fish and Wildlife Office in Carlsbad, California.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Regulation Promulgation

Accordingly, we amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; 4201–4245, unless otherwise noted.

■ 2. Amend § 17.11(h), the List of Endangered and Threatened Wildlife, under MAMMALS, by:

■ a. Removing the entries for "Fox, San Miguel Island", "Fox, Santa Cruz Island", and "Fox, Santa Rosa Island"; and

■ b. Revising the entry for "Fox, Santa Catalina Island".

The revision reads as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
MAMMALS				
* *	*	* *		* *
Fox, Santa Catalina Island	*Urocyon littoralis catalinae*	Wherever found	T	69 FR 10335; 3/5/2004 81 FR [*Insert **Federal Register** page where the document begins*]; 8/12/2016 50 CFR 17.95(a)^{CH}
* *	*	* *		* *

§ 17.95 [Amended]

■ 3. Amend § 17.95(a) by removing the entries for "San Miguel Island Fox (*Urocyon littoralis littoralis*)", "Santa Cruz Island Fox (*Urocyon littoralis santacruzae*)", and "Santa Rosa Island Fox (*Urocyon littoralis santarosae*)".

Dated: July 21, 2016.

Stephen Guertin,

Acting Director, Fish and Wildlife Service.

[FR Doc. 2016–18778 Filed 8–11–16; 8:45 am]

BILLING CODE 4333–15–P

Proposed Rules

Federal Register
Vol. 81, No. 156
Friday, August 12, 2016

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 319

[Docket No. APHIS–2015–0091]

RIN 0579–AE24

Importation of Orchids in Growing Media From the Republic of Korea Into the Continental United States

AGENCY: Animal and Plant Health Inspection Service, Department of Agriculture.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the regulations governing the importation of plants for planting to add orchid plants of the genera *Phalaenopsis* and *Cymbidium* from the Republic of Korea to the list of plants that may be imported into the continental United States in an approved growing medium, subject to specified growing, inspection, and certification requirements. We are taking this action in response to a request from the Republic of Korea and after determining that the plants could be imported under certain conditions, without resulting in the introduction into, or the dissemination within, the United States of a plant pest or noxious weed.

DATES: We will consider all comments that we receive on or before October 11, 2016.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0091.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2015–0091, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0091* or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Mr. William Aley, Senior Regulatory Specialist, Plants for Planting Policy, PPQ, APHIS, 4700 River Road, Unit 133, Riverdale, MD 20737; (301) 851–2130.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 7 CFR part 319 prohibit or restrict the importation into the United States of certain plants and plant products into the United States to prevent the introduction of plant pests and noxious weeds. The regulations in "Subpart—Plants for Planting," §§ 319.37 through 319.37–14 (referred to below as the regulations) contain, among other things, prohibitions and restrictions on the importation of plants, plant parts, and seeds for propagation.

Paragraph (a) of § 319.37–8 of the regulations requires, with certain exceptions, that plants offered for importation into the United States be free of sand, soil, earth, and other growing media. This requirement is intended to help prevent the introduction of plant pests that might be present in the growing media; the exceptions to the requirement take into account factors that mitigate that plant pest risk. Those exceptions, which are found in paragraphs (b) through (e) of § 319.37–8, consider either the origin of the plants and growing media (paragraph (b)), the nature of the growing media (paragraphs (c) and (d)), or the use of a combination of growing conditions, approved media, inspections, and other requirements (paragraph (e)).

Paragraph (e) of § 319.37–8 provides conditions under which certain plants established in growing media may be imported into the United States. In addition to specifying the types of plants that may be imported, § 319.37–8(e) also:

- Specifies the types of growing media that may be used;
- Requires plants to be grown in accordance with written agreements between the Animal and Plant Health Inspection Service (APHIS) and the national plant protection organization (NPPO) of the country where the plants are grown and between the foreign NPPO and the grower;
- Requires the plants to be rooted and grown in a greenhouse that meets certain requirements for pest exclusion and that is used only for plants being grown in compliance with § 319.37–8(e);
- Restricts the source of the seeds or parent plants used to produce the plants, and requires grow-out or treatment of parent plants imported into the exporting country from another country;
- Specifies the sources of water that may be used on the plants, the height of the benches on which the plants must be grown, and the conditions under which the plants must be stored and packaged; and
- Requires that the plants be inspected in the greenhouse and found free of evidence of plant pests no more than 30 days prior to the exportation of the plants.

A phytosanitary certificate issued by the NPPO of the country in which the plants were grown that declares that the above conditions have been met, must accompany the plants at the time of importation. These conditions have been used successfully to mitigate the risk of pest introduction associated with the importation into the United States of approved plants established in growing media.

Currently, orchid plants of the genera *Cymbidium* and *Phalaenopsis* may only be imported into the United States from the Republic of Korea as bare root plants, in accordance with § 319.37–2. The NPPO of the Republic of Korea has requested that importation into the United States of those plants in growing media be allowed under the provisions of § 319.37–8.

The regulations in § 319.37–8(g) provide that requests such as the one made by the NPPO of the Republic of Korea be evaluated by APHIS using a pest risk assessment (PRA) that uses specific pest risk evaluation standards that are based on pest risk analysis guidelines established by the International Plant Protection Convention of the United Nations' Food and Agriculture Organization. Such analyses are conducted to determine the plant pest risks associated with each requested plant article and to determine whether or not APHIS should propose to allow the requested plant article established in growing media to be imported into the United States. In accordance with § 319.37–8(g), APHIS has conducted the required PRA, which can be viewed online on the *Regulations.gov* Web site or in our reading room (see **ADDRESSES** above for instructions for accessing *Regulations.gov*).

In the PRA, titled "Importation of *Cymbidium* spp. and *Phalaenopsis* spp. Orchid Plants in Approved Growing Media from Republic of Korea into the Continental United States," APHIS identified that six quarantine pests present in the Republic of Korea could potentially follow the import pathway:

Moths

- *Spodoptera litura* (Fabricius)
- *Dichromothrips smithi* (Zimmermann)
- *Thrips palmi* (Karny)
- *Pseudococcus dendrobiorum* (Williams)

Slug

- *Deroceras varians* (Adams)

Fungi

- *Colletotrichum boninense* (Moriwaki)

The PRA identified *P. dendrobiorum* as having a medium pest risk potential of following the pathway on *Cymbidium* spp. and *Phalaenopsis* plants from the Republic of Korea. The remaining five plant pests (*S. litura, D. smithi, T. palmi, D. varians,* and *C. boninense*) were rated as having a high pest risk potential.

However, the PRA acknowledged that the risk presented by these plant pests is consistent with pests associated with any propagative orchid materials. Further, it is important to note that those plant pest risks are present in the absence of the mitigative effects of the requirements in § 319.37–8(e), which are designed to establish and maintain a pest-free production environment and ensure the use of pest-free seeds or parent plants. Given that, the risk management document (RMD) concluded that the safeguards in § 319.37–8(e) would allow the safe importation of *Cymbidium* spp. and *Phalaenopsis* spp. plants from the Republic of Korea provided that the plants are established in an approved growing medium and meet all other applicable conditions of § 319.37–8(e). Based on the findings of the PRA and RMD, we have determined that the application of the measures required under § 319.37–8(e) will prevent the introduction or dissemination of plant pests into the United States.

Accordingly, we are proposing to amend the regulations in § 319.37–8(e) by adding *Cymbidium* spp. and *Phalaenopsis* spp. plants from the Republic of Korea to the list of plants established in an approved growing medium that may be imported into the United States. The plants would have to be produced, handled, and imported in accordance with the requirements of § 319.37–8(e) and be accompanied at the time of importation by a phytosanitary certificate issued by the NPPO of the Republic of Korea that declares that those requirements have been met.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

In accordance with the Regulatory Flexibility Act, we have analyzed the potential economic effects of this action on small entities. The analysis is summarized below. Copies of the full analysis are available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT** or on the *Regulations.gov* Web site (see **ADDRESSES** above for instructions for accessing *Regulations.gov*).

Orchids are the single largest group of potted flowering plants sold in the United States, comprising about $266 million of the $788 million in 2014 sales for this industry. In 2014, *Phalaenopsis* spp. comprised 57 percent of orchid sales. Although *Cymbidium* spp. are popular in other parts of the world, the quantity of potted *Cymbidium* spp. sold in the United States is small when compared to other varieties of orchids.

The proposed rule would enable Korean exporters to provide higher-valued, mature potted plants directly to wholesalers and retailers. However, such a scenario is considered unlikely, given the technical challenges and marketing costs incurred when shipping finished plants in pots. A more likely scenario is for the Republic of Korea to export immature plants as bare root plants or in approved growing media to U.S. nurseries to grow and sell as finished plants.

The United States imported more than 6,760 metric tons (MT) of live orchids valued at about $83 million in 2014, with Taiwan supplying almost 84 percent. The Republic of Korea expects to export to the United States from 2 to 5 million *Phalaenopsis* plants and about 1 million *Cymbidium* plants per year in approved growing media. This combined number of plants, 3 to 6 million, is estimated to equal more than 2,000 MT to 4,000 MT per year. This amount seems disproportionate to the Republic of Korea's history of orchid exports worldwide, which have declined from 2,936 MT in 2010 to 806 MT in 2014. The Republic of Korea exported only 1.3 MT of bare-rooted orchid plants to the United States in 2014.

We expect the quantity of orchids in approved growing media imported from the Republic of Korea will also be limited because of the U.S. market's competitive environment. Import levels would depend on the ability of Korean producers and exporters to cover their production, transportation, and marketing costs given U.S. market prices. U.S. nurseries that purchased the Korean orchids in approved growing media would benefit from their improved quality and reduced production time in comparison to bare-rooted plants. The proposed rule would increase competition for U.S. producers and importers of immature *Phalaenopsis* spp. and *Cymbidium* spp. plants.

U.S. orchid producers numbered 158 in 2012. Of those producers, it is unknown how many are small entities. Given the relatively small quantity of orchid plants in approved growing media that we expect to be imported from the Republic of Korea, the Administrator of the Animal and Plant Health Inspection Service has determined that this action, if promulgated, will not have a significant economic impact on a substantial number of small entities.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

National Environmental Policy Act

To provide the public with documentation of APHIS' review and analysis of any potential environmental impacts associated with the proposed importation of *Phalaenopsis* spp. and *Cymbidium* spp. orchid varieties from the Republic of Korea into the continental United States, we have prepared an environmental assessment. The environmental assessment was prepared in accordance with: (1) The National Environmental Policy Act of

1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) United States Department of Agriculture (USDA) regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

The environmental assessment may be viewed on the *Regulations.gov* Web site or in our reading room. Comments on the environmental assessment can be submitted following the instructions under **ADDRESSES**. (A link to *Regulations.gov* and information on the location and hours of the reading room are provided under the heading **ADDRESSES** at the beginning of this proposed rule.) In addition, copies may be obtained by calling or writing to the individual listed under **FOR FURTHER INFORMATION CONTACT**.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), reporting and recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send comments on the Information Collection Request (ICR) to OMB's Office of Information and Regulatory Affairs via email to *oira_submissions@omb.eop.gov,* Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. APHIS–2015–0091. Please send a copy of your comments to the USDA using one of the methods described under **ADDRESSES** at the beginning of this document.

APHIS is proposing to amend the regulations governing the importation of plants for planting to add orchid plants of the genera *Phalaenopsis* and *Cymbidium* from the Republic of Korea to the list of plants that can be imported into the continental United States in an approved growing medium, subject to specified growing, inspection, and certification requirements. APHIS is taking this action after determining that the plants could be imported under certain conditions, without resulting in the introduction into, or the dissemination within, the United States of a plant pest or noxious weed.

Adding orchid plants of the genera *Phalaenopsis* and *Cymbidium* from the Republic of Korea to the list of plants that can be imported into the continental United States in growing media will require information collection activities, such as phytosanitary certificates, written agreements, and inspections.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning these information collection activities. APHIS needs this outside input to help accomplish the following:

(1) Evaluate whether the information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of burden of the information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond, (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission or responses).

Estimate of burden: Public reporting burden for this collection of information is estimated to average 0.56 hours per response.

Respondents: Importers, shippers, and the NPPO of the Republic of Korea.

Estimated number of respondents: 3.

Estimated number of responses per respondent: 139.

Estimated annual number of responses: 416.

Estimated total annual burden on respondents: 232.

(Due to rounding, the total annual burden hours may not equal the product of the annual number of responses multiplied by the average reporting burden per response.)

A copy of the information collection may be viewed on the *Regulations.gov* Web site or in our reading room. (A link to *Regulations.gov* and information on the location and hours of the reading room are provided under the heading **ADDRESSES** at the beginning of this proposed rule.) Copies can also be obtained from Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2727. APHIS will respond to any ICR-related comments in the final rule. All comments will also become a matter of public record.

E-Government Act Compliance

APHIS is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this proposed rule, please contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2727.

List of Subjects in 7 CFR Part 319

Coffee, Cotton, Fruits, Imports, Logs, Nursery stock, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Rice, Vegetables.

Accordingly, we propose to amend 7 CFR part 319 as follows:

PART 319—FOREIGN QUARANTINE NOTICES

■ 1. The authority citation for part 319 continues to read as follows:

Authority: 7 U.S.C. 450, 7701–7772, and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

■ 2. In § 319.37–8, paragraph (e) is amended as follows:

■ a. In the introductory text, by adding a new entry for "*Cymbidium* spp, from the Republic of Korea" in alphabetical order and revising the entry for *Phalaenopsis* spp.; and

■ b. By revising paragraph (e)(2)(xiii).

The addition and revisions read as follows:

§ 319.37–8 Growing media.

* * * * *

(e) * * *

Cymbidium spp. from the Republic of Korea

* * * * *

Phalaenopsis spp. from Taiwan, the People's Republic of China, and the Republic of Korea.

* * * * *

(2) * * *

(xiii) Plants for planting of *Phalaenopsis* spp. from the People's Republic of China and *Phalaenopsis* spp. and *Cymbidium* spp. from the Republic of Korea may only be imported into the continental United States, and may not be imported or moved into Hawaii or the territories of the United States.

* * * * *

Done in Washington, DC, this 9th day of August 2016.

Jere L. Dick,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2016–19224 Filed 8–11–16; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF ENERGY

10 CFR Part 820

[Docket No. EA–RM–16–PRDNA]

RIN 1992–AA52

Procedural Rules for DOE Nuclear Activities

AGENCY: Office of Enterprise Assessments, Office of Enforcement, Office of Nuclear Safety Enforcement, Department of Energy.

ACTION: Notice of proposed rulemaking.

SUMMARY: The U.S. Department of Energy (DOE) is proposing to amend its Procedural Rules for DOE Nuclear Activities to clarify that the Department may assess civil penalties against certain contractors and subcontractors for violations of the prohibition against retaliating against an employee who reports violations of law, mismanagement, waste, abuse, or dangerous/unsafe workplace conditions, among other protected activities, concerning nuclear safety (referred to as "whistleblowers"). Specifically, this proposed rule would clarify that the prohibition against whistleblower retaliation is a DOE Nuclear Safety Requirement to the extent that it concerns nuclear safety. The proposed rule would also explain the circumstances under which DOE would investigate alleged violations of this prohibition. The proposed rule would also delineate which DOE regulations are DOE Nuclear Safety Requirements.

DATES: DOE will accept comments, data, and information regarding this notice of proposed rulemaking (NOPR) submitted on or before September 12, 2016.

ADDRESSES: Any comments submitted must identify the NOPR for Procedural Rules for DOE Nuclear Activities and provide docket number EA–RM–16–PRDNA and/or regulatory information number (RIN) 1992–AA52. Comments may be submitted using any of the following methods:

1. *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
2. *Email: part820rulemaking@hq.doe.gov.* Include the docket number and/or RIN in the subject line of the message. Submit electronic comments in Microsoft Word, or PDF file format, and avoid the use of special characters or any form of encryption.
3. *Postal Mail:* EA–10/Germantown Building, U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585–1290. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

As a result of potential delays in the receipt and processing of mail sent through the U.S. Postal Service, DOE encourages respondents to submit comments electronically to ensure timely receipt.

For detailed instructions on submitting comments and additional information on the rulemaking process, see section III of this document (Public Participation).

Docket: The docket, which includes **Federal Register** notices, public meeting attendee lists and transcripts, comments received, and other supporting documents/materials, is available for review at *http://www.regulations.gov.* All documents in the docket are listed in the *www.regulations.gov* index. However, some documents listed in the index may not be publicly available, such as those containing information that is exempt from public disclosure. A link to the docket Web page can be found at: *http://energy.gov/ea/office-enterprise-assessments.* This Web page will contain a link to the docket for this proposed rulemaking on the *www.regulations.gov* site. The *www.regulations.gov* Web page contains simple instructions on how to access all documents, including public comments, in the docket. See section III for further information on how to submit comments through *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT:

Steven Simonson, U.S. Department of Energy, Office of Enterprise Assessments/Germantown Building, 1000 Independence Ave. SW., Washington, DC 20585–1290. Phone: (301) 903–2816. Email: *Steven.Simonson@hq.doe.gov.*

K.C. Michaels, U.S. Department of Energy, Office of the General Counsel, 1000 Independence Ave. SW., Washington, DC 20585–0121. Phone: (202) 586–3430. Email: *Kenneth.Michaels@hq.doe.gov.*

SUPPLEMENTARY INFORMATION:

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I. Authority and Background
II. Discussion of Proposed Amendment
III. Public Participation
IV. Procedural Issues and Regulatory Review

I. Authority and Background

Pursuant to the Atomic Energy Act of 1954 (AEA) (42 U.S.C. 2011 *et seq.*), DOE has issued regulations governing nuclear safety management (at 10 CFR part 830) and occupational radiation protection (at 10 CFR part 835). Section 234A of the AEA (42 U.S.C. 2282a) authorizes DOE to impose civil penalties for violations of these regulations. Specifically, section 234A authorizes civil penalties against contractors, subcontractors, and suppliers that are covered by an indemnification agreement under section 170.d. of the AEA (42 U.S.C. 2210(d)) (commonly known as the Price-Anderson Act) that violate DOE rules, regulations, or orders "related to nuclear safety." DOE has issued Procedural Rules for DOE Nuclear Activities at 10 CFR part 820 (part 820), which establishes a process for imposing civil penalties under section 234A.

Separate from part 820, DOE has also issued regulations at 10 CFR part 708 (part 708) that prohibit a contractor or subcontractor from retaliating against employees for reporting violations of law, mismanagement, waste, abuse, or dangerous/unsafe workplace conditions, participating in proceedings, or refusing to participate in an activity that may constitute a violation of law or cause a reasonable fear of injury (referred to as "whistleblowers"). These regulations establish an affirmative duty on the part of contractors not to retaliate against whistleblowers; and establish a process for an employee alleging retaliation to file a claim for reinstatement, transfer-preference, back-pay, and legal fees among other forms of relief.

DOE is proposing to amend part 820 to clarify that DOE may impose civil penalties against a contractor or subcontractor for violating the prohibition against whistleblower retaliation found in part 708, to the extent it concerns nuclear safety. The proposed rule would not alter the existing procedures for imposing civil penalties, but would establish requirements specific to whistleblower retaliation concerning nuclear safety. The proposed rule would also provide, in the text of part 820, a list of all other DOE Nuclear Safety Requirements.

II. Discussion of Proposed Amendment

A. What are DOE Nuclear Safety Requirements and when may DOE impose civil penalties?

The current version of part 820 includes a definition for "DOE Nuclear Safety Requirements," and it states that DOE has authority to impose civil penalties for violations of any DOE Nuclear Safety Requirement set forth in the Code of Federal Regulations, Compliance Orders issued under subpart C to part 820, and any program, plan, or other provision required to implement one of these rules or orders.[1]

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[1] The use of the word "order" in this context refers to Compliance Orders issued under subpart

Continued

The rule does not identify the particular rules and regulations that DOE regards as DOE Nuclear Safety Requirements.

DOE proposes to amend part 820 to update the definition of DOE Nuclear Safety Requirements, to add a new section to part 820, and to amend the guidance in appendix A to part 820—General Statement of Enforcement Policy. In particular, DOE proposes that the following are enforceable DOE Nuclear Safety Requirements to the extent they concern nuclear safety:

10 CFR part 830 (nuclear safety management);

10 CFR part 835 (occupational radiation protection);

10 CFR 820.11 (information accuracy requirements);

Compliance Orders issued pursuant to 10 CFR part 820, subpart C;

10 CFR 708.43 (duty of contractors not to retaliate against whistleblowers).

The lack of a definitive list of regulations included in the definition of DOE nuclear safety requirements in the text of part 820 has led to a question regarding the scope of DOE's authority to issue civil penalties for violations of these regulations, particularly the prohibition against whistleblower retaliation in part 708. To address this question, DOE proposes to amend part 820 to clarify that part 830, part 835, § 820.11, Compliance Orders issued pursuant to subpart C to part 820, and § 708.43 as it concerns nuclear safety each represent DOE Nuclear Safety Requirements and that DOE may assess civil penalties for violations of these rules. This amendment is consistent with the original intent in promulgating part 820, as evidenced by appendix A of this part, the preambles to previous rulemakings (*e.g.* 58 FR 43680, 43681 (Aug. 17, 1993)).

DOE considers each of these provisions to be a DOE Nuclear Safety Requirement and has previously exercised enforcement activity on the basis of violations of these regulations. Parts 830 and 835 both have a clear connection to nuclear safety in that each regulation directly and explicitly governs the conduct of persons whose conduct may affect nuclear safety. Further, part 830 states explicitly that the requirements of part 830 are DOE Nuclear Safety Requirements and 10 CFR 830.5 provides that violations of part 830 may be enforced through civil penalties in accordance with part 820.

Compliance Orders issued pursuant to subpart C to part 820 and § 820.11 also have a clear connection to nuclear safety. Subpart C allows the Secretary of Energy to order any person involved in a DOE nuclear activity to remediate a situation that violates or potentially violates the AEA, another statute relating to a DOE nuclear activity, or a DOE Nuclear Safety Requirement. Because the underlying violations would involve nuclear safety, Compliance Orders issued under subpart C govern conduct that relates to and may affect nuclear safety. Section 820.11 requires that information pertaining to a nuclear activity that is provided to or maintained for inspection by DOE must be complete and accurate in all respects and prohibits any person involved in a nuclear activity from concealing or destroying information concerning a violation of a DOE Nuclear Safety Requirement. If information regarding a nuclear activity is incomplete or inaccurate, this impedes DOE's ability to conclude that a contractor is adhering to proper safety precautions. Likewise, if a person willfully destroys information regarding a safety violation, it becomes less likely that the violation will be rectified.

Section 708.43 establishes an affirmative duty on the part of DOE contractors (including subcontractors) not to retaliate against whistleblowers. Section 708.36 provides various forms of relief to whistleblower employees. Providing this relief is important, but the Department also has a strong interest in preventing whistleblower retaliation and ensuring that workers feel free to raise important safety concerns. DOE and its contractors rely to a significant extent on workers to bring attention to unsafe conditions. If workers witness any retaliation against an employee for raising a potential nuclear safety issue, it may contribute to a chilled work environment in which workers do not feel free to report such issues. Accordingly, § 708.43, as it applies to activities at DOE nuclear facilities that concern nuclear safety, constitutes a DOE Nuclear Safety Requirement.

B. What is the effect of administrative and judicial whistleblower proceedings on DOE's enforcement process?

An employee alleging retaliation by a DOE contractor or subcontractor has several different mechanisms to file a claim for relief, including filing a claim pursuant to part 708, with the DOE Office of the Inspector General, with the Department of Labor under 29 CFR part 24, or in federal or state court. For most of these mechanisms, a contractor employee may seek a "make whole" remedy including reinstatement, transfer-preference, back-pay, and legal fees, among other forms of compensation. DOE considers the imposition of civil penalties for whistleblower retaliation as a complementary process to these proceedings. Relief to contractor employees who have been found to suffer retaliation is important, but DOE also has a separate and strong interest in deterring future whistleblower retaliation in connection with nuclear safety issues. A "make whole" remedy to the employee may not be sufficiently punitive to deter future retaliation against whistleblowers. In these situations, separate enforcement with the possibility of imposing civil penalties would allow DOE to craft a remedy that is specifically designed to address these safety concerns.

As a matter of regulatory concern, DOE recognizes that conducting enforcement proceedings concerning retaliation in parallel with administrative or judicial proceedings may lead to conflicting results. DOE's current enforcement policy explains that DOE will generally await the completion of an administrative proceeding before deciding whether to take action. DOE proposes to codify this policy into the regulatory text with respect to proceedings before DOE under part 708, the DOE Office of the Inspector General under 41 U.S.C. 4705 or 4712, the Department of Labor under 29 CFR part 24, or a federal or state court. Specifically, DOE proposes that it will not take any action under part 820 with respect to alleged retaliation until after the deadlines have passed for filing a claim under part 708 or 29 CFR part 24—*i.e.* 180 days after the alleged violation occurs.[2] If an administrative or judicial proceeding is filed after DOE has already initiated any action under part 820, DOE will immediately suspend its activities under part 820 until the issuance of a final decision in the proceeding—including the exhaustion of appeals. In such instances, DOE will not take any action under part 820 until sixty days after a final decision in an administrative or judicial proceeding finds that a retaliation occurred.

DOE proposes that it will generally exercise enforcement discretion that is consistent with the final decision of an

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C to part 820, not to orders issued under the DOE Directives Program.

[2] For a part 708 claim, the employee must file within 90 days after the employee knew or reasonably should have known about the alleged retaliation. For a claim under 29 CFR part 24, the employee must file within 180 days of an alleged violation prohibited by section 211 of the Energy Reorganization Act of 1974 (42 U.S.C. 5851). There is a three-year deadline for filing a complaint with the Inspector General under 41 U.S.C. 4712, but there is no explicit deadline under 41 U.S.C. 4705. Statutes of limitations before federal and state courts vary.

agency or court. If a final decision finds that retaliation occurred, DOE will consider whether that retaliation constitutes a violation of § 708.43, and if so, whether to take action under part 820. On the other hand, if a final decision finds that no retaliation occurred, DOE will not take any further action under part 820 with respect to the alleged retaliation unless DOE becomes aware of significant new information that was not available in the prior proceeding.

DOE is aware that the various statutory and regulatory prohibitions against whistleblower retaliation are not identical. Section 708.43 prohibits retaliation against an employee who engages in one of a number of specified activities. It is conceivable that a contractor could retaliate against an employee for an action that is not protected under § 708.43, but that is protected under a different statutory or regulatory prohibition. Therefore, in the event that a final decision finds that a prohibited retaliation has taken place, DOE will make a determination of whether that retaliation also constitutes a violation of § 708.43 before pursuing remedial measures under part 820 against the contractor.

C. What is DOE's enforcement policy regarding whistleblower retaliation?

Section XIII to appendix A to part 820 currently sets forth DOE's Whistleblower Enforcement Policy. As mentioned in this preamble, this appendix is a general statement of policy and is not binding on DOE or its contractors. In addition to codifying DOE's existing policy to await the completion of administrative proceedings, as described in this preamble, DOE also proposes to codify two other statements of the enforcement policy into a new section of part 820 governing whistleblower enforcement. Specifically, DOE proposes to codify paragraphs d and e of section XIII, which provide that DOE may collect information gathered during administrative proceedings and give appropriate weight to that information in DOE's enforcement process, respectively. DOE also proposes to codify paragraph k of section XIII, which provides that the commencement of an administrative or judicial proceeding regarding an alleged retaliation does not prevent DOE from investigating violations of DOE Nuclear Safety Requirements other than § 708.43.

Under this NOPR, DOE is also proposing amendments to section XIII of appendix A to conform with the proposed changes to the regulatory text of part 820.

III. Public Participation

DOE will accept comments, data, and information regarding this proposed rule submitted on or before the date provided in the **DATES** section at the beginning of this proposed rule. Interested parties may submit comments, data, and other information using any of the methods described in the **ADDRESSES** section at the beginning of this proposed rule. Please refer to specific proposed rule provisions, if possible.

If you submit information that you believe to be exempt by law from public disclosure, you should submit one complete copy marked "confidential," and one copy marked "non-confidential" with the information believed to be confidential deleted. DOE is responsible for the final determination with regard to disclosure or nondisclosure of the information and for treating it accordingly under the DOE Freedom of Information regulations at 10 CFR 1004.11. Factors of interest to DOE when evaluating requests to treat submitted information as confidential include: (1) A description of the items; (2) whether and why such items are customarily treated as confidential within the industry; (3) whether the information is generally known or available from other sources; (4) whether the information has previously been made available to others without obligation concerning its confidentiality; (5) an explanation of the competitive injury to the submitting person that would result from public disclosure; (6) when such information might lose its confidential character due to the passage of time; and (7) why disclosure of the information would be contrary to the public interest.

It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

DOE has determined that this rulemaking does not raise the kinds of substantial issues or impacts that, pursuant to 42 U.S.C. 7191, would require DOE to provide an opportunity for oral presentation of views, data and arguments. Therefore, DOE has not scheduled a public hearing on these proposed amendments to part 820.

IV. Procedural Issues and Regulatory Review

A. Review Under Executive Order 12866

This notice of proposed rulemaking has been determined not to be a significant regulatory action under Executive Order 12866, "Regulatory Planning and Review," 58 FR 51735 (Oct. 4, 1993). Accordingly, this notice of proposed rulemaking was not subject to review by the Office of Information and Regulatory Affairs of the Office of Management and Budget.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by Executive Order 13272, "Proper Consideration of Small Entities in Agency Rulemaking," 67 FR 53461 (Aug. 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of the General Counsel's Web site (*http://energy.gov/gc/office-general-counsel*).

DOE has reviewed this proposed rule under the provisions of the Regulatory Flexibility Act and the procedures and policies published on February 19, 2003. The proposed rule would amend DOE's Procedural Rules for DOE Nuclear Activities to clarify that DOE may assess civil penalties against certain contractors and subcontractors for violations of the prohibition against retaliating against whistleblowers. While the amended part 820 would expose small entities that are contractors and subcontractors to potential liability for civil penalties, DOE does not expect that a substantial number of these entities will violate a DOE Nuclear Safety Requirement resulting in the imposition of a civil penalty. On this basis, DOE certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities. Accordingly, DOE has not prepared a regulatory flexibility analysis for this rulemaking. DOE's certification and supporting statement of factual basis will be provided to the Chief Counsel for Advocacy of the Small Business Administration pursuant to 5 U.S.C. 605(b).

C. Paperwork Reduction Act

This proposed rule would not impose new information or record keeping requirements. Accordingly, OMB clearance is not required under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

D. National Environmental Policy Act

DOE has determined that this proposed rule is covered under the Categorical Exclusion in DOE's National Environmental Policy Act regulations at paragraph A.5 of appendix A to subpart D, 10 CFR part 1021, which applies to rulemaking that interprets or amends an existing rule or regulation without changing the environmental effect of the rule or regulation that is being amended. The proposed rule would amend DOE's regulations on civil penalties with respect to certain DOE contractors and subcontractors in order to clarify that civil penalties are available for violations of the prohibition against whistleblower retaliation found in § 708.43 that concern nuclear safety. These proposed amendments are procedural and would not change the environmental effect of part 820. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

E. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1531 *et seq.,* requires each Federal agency, to the extent permitted by law, to prepare a detailed assessment of the effects of any Federal mandate in an agency rule that may result in costs to State, local, or tribal governments, or to the private sector, of $100 million or more (adjusted annually for inflation) in any one year. 2 U.S.C. 1532. While the proposed rule may expose DOE contractors and subcontractors to potential liability for civil penalties for retaliating against a whistleblower in connection with a protected activity relating to nuclear safety, DOE does not expect that these civil penalties will approach $100 million in any single year. Therefore, the requirements of Title II of the Unfunded Mandates Reform Act of 1995 do not apply.

F. Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999, 5 U.S.C. 601 note, requires Federal agencies to issue a Family Policymaking Assessment for any proposed rule that may affect family wellbeing. While this proposed rule would apply to individuals who may be members of a family, the rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

G. Executive Order 13132

Executive Order 13132, "Federalism," 64 FR 43255 (Aug. 4, 1999), imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. Agencies are required to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and carefully assess the necessity for such actions. DOE has examined this proposed rule and has determined that it would not preempt State law and would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. No further action is required by Executive Order 13132.

H. Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, "Civil Justice Reform," 61 FR 4729 (Feb. 7, 1996), imposes on Executive agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; and (3) provide a clear legal standard for affected conduct rather than a general standard and promote simplification and burden reduction. With regard to the review required by section 3(a), section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this proposed rule meets the relevant standards of Executive Order 12988.

I. Treasury and General Government Appropriations Act, 2001

The Treasury and General Government Appropriations Act, 2001, 44 U.S.C. 3516 note, provides for agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67 FR 62446 (Oct. 7, 2002). DOE has reviewed this notice of proposed rulemaking under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

J. Executive Order 13211

Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use," 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to the Office of Information and Regulatory Affairs (OIRA) a Statement of Energy Effects for any proposed significant energy action. A "significant energy action" is defined as any action by an agency that promulgates or is expected to lead to promulgation of a final rule, and that: (1) Is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy, or (3) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use. This regulatory action has been determined to not be a significant regulatory action, and it would not have an adverse effect on the supply, distribution, or use of energy. Thus, this action is not a significant energy action. Accordingly, DOE has not prepared a Statement of Energy Effects.

K. Approval of the Office of the Secretary

The Secretary of Energy has approved the publication of this proposed rule.

List of Subjects in 10 CFR Part 820

Administrative practice and procedure, Enforcement, Government contracts, Nuclear safety, Penalties, Whistleblowing.

Issued in Washington, DC, on August 5, 2016.

Glenn S. Podonsky,

Director, Office of Enterprise Assessments.

For the reasons stated in the preamble, DOE hereby proposes to amend part 820 of chapter III of title 10 of the Code of Federal Regulations as set forth below:

PART 820—PROCEDURAL RULES FOR DOE NUCLEAR ACTIVITIES

■ 1. The authority citation for part 820 continues to read as follows:

Authority: 42 U.S.C. 2201; 2282(a); 7191; 28 U.S.C. 2461 note; 50 U.S.C. 2410.

■ 2. Section 820.2 is amended by revising the definition for "DOE Nuclear Safety Requirements" to read as follows:

§ 820.2 Definitions.

* * * * *

DOE Nuclear Safety Requirements means the set of rules, regulations, orders, and other requirements relating to nuclear safety adopted by DOE to govern the conduct of persons in connection with any DOE nuclear activity and includes any program, plan, or other provision required to implement these rules, regulations, orders, or other requirements. DOE Nuclear Safety Requirements include the following, to the extent that subject activities concern nuclear safety:

(i) 10 CFR part 830;

(ii) 10 CFR part 835;

(iii) 10 CFR 820.11;

(iv) Compliance Orders issued pursuant to 10 CFR part 820, subpart C; and

(v) 10 CFR 708.43.

* * * * *

■ 3. Section 820.14 is added to subpart A to read as follows:

§ 820.14 Whistleblower protection.

(a) *Covered acts.* An act of retaliation (as defined in 10 CFR 708.2) by a DOE contractor, prohibited by 10 CFR 708.43, that results from a DOE contractor employee's involvement in an activity listed in 10 CFR 708.5(a) through (c) may constitute a violation of a DOE Nuclear Safety Requirement if it concerns nuclear safety.

(b) *Commencement of investigation.* The Director may not initiate an investigation or take any other action under this part with respect to an alleged act of retaliation by a DOE contractor until 180 days after an alleged violation of 10 CFR 708.43 occurs.

(c) *Administrative or judicial proceedings.* The Director shall immediately suspend any ongoing activities under this part and suspend any time limits under this part when an administrative or judicial proceeding commences based on the same alleged act of retaliation. While an administrative or judicial proceeding, including appeals, is pending, the Director may not exercise any authority under this part based on an alleged violation of 10 CFR 708.43, including issuing enforcement letters, subpoenas, orders to compel attendance, Consent Orders, Preliminary Notices of Violation, or Final Notices of Violation. Once such a proceeding commences, the Director shall not conduct any activities under this part until sixty days after a final decision of an agency or court finds that a retaliation occurred.

(d) *Final decision.* For the purposes of this section, a final decision of an agency or court includes any of the following:

(1) A final agency decision pursuant to 10 CFR part 708;

(2) A final decision or order of the Secretary of Labor pursuant to 29 CFR part 24;

(3) A decision by the Secretary upon a report by the Inspector General;

(4) A decision by a federal or state court.

(e) *Evidentiary record.* If a final decision of an agency or court finds that retaliation occurred, the Director may obtain and use information collected as part of those proceedings. The Director has discretion to give appropriate weight to information obtained from these proceedings and to initiate and conduct further investigation if the Director deems necessary, particularly with regard to the relationship between the retaliation and nuclear safety.

(f) *Underlying nuclear safety requirements.* Notwithstanding the commencement of an administrative or judicial proceeding based on an alleged act of retaliation, this section shall not prevent the Director from taking any action consistent with this part regarding compliance with DOE Nuclear Safety Requirements other than 10 CFR 708.43.

■ 4. Section 820.20 is amended by revising paragraphs (a) and (b) to read as follows:

§ 820.20 Purpose and scope.

(a) *Purpose.* This subpart establishes the procedures for investigating the nature and extent of violations of DOE Nuclear Safety Requirements, for determining whether a violation of DOE Nuclear Safety Requirements has occurred, for imposing an appropriate remedy, and for adjudicating the assessment of a civil penalty.

(b) *Basis for civil penalties.* DOE may assess civil penalties against any person subject to the provisions of this part who has entered into an agreement of indemnification under 42 U.S.C. 2210(d) (or any subcontractor or supplier thereto), unless exempted from civil penalties as provided in paragraph (c) of this section, on the basis of a violation of a DOE Nuclear Safety Requirement.

* * * * *

■ 5. Appendix A to part 820 is amended by revising section XIII to read as follows:

Appendix A to Part 820—General Statement of Enforcement Policy

* * * * *

XIII. Whistleblower Enforcement Policy

a. DOE contractors may not retaliate against any employee because the employee has taken any actions listed in 10 CFR 708.5(a) through(c), including disclosing information, participating in proceedings, or refusing to participate in certain activities. DOE contractor employees may seek relief for allegations of retaliation through one of several mechanisms, including filing a complaint with DOE pursuant to 10 CFR part 708 (part 708), the Department of Labor (DOL) under sec. 211 of the Energy Reorganization Act (sec. 211), implemented in 29 CFR part 24, or the DOE Inspector General (IG).

b. An act of retaliation by a DOE contractor, prohibited by 10 CFR 708.43, that results from a DOE contractor employee's involvement in an activity listed in 10 CFR 708.5(a) through (c), may constitute a violation of a DOE Nuclear Safety Requirement under 10 CFR part 820 if it concerns nuclear safety. To avoid the potential for inconsistency with one of the mechanisms available to an aggrieved DOE contractor employee alleging retaliation referenced in section XIII.a, the Director will not take any action under this part with respect to an alleged violation of 10 CFR 708.43 until a request for relief under one of these mechanisms, if any, has been fully adjudicated, including appeals. With respect to an alleged retaliation, the Director will generally only take action that is consistent with the findings of a final decision of an agency or court. If a final decision finds that retaliation occurred, the Department will consider whether that retaliation constitutes a violation of § 708.43, and if so, whether to take action under part 820. If a final decision finds that no retaliation occurred, the Director will generally not take any action under part 820 with respect to the alleged retaliation absent significant new information that was not available in the prior proceeding.

c. DOE encourages its contractors to cooperate in resolving whistleblower complaints raised by contractor employees in a prompt and equitable manner. Accordingly, in considering what remedy is appropriate for an act of retaliation concerning nuclear safety, the Director will take into account the extent to which a contractor cooperated in proceedings for remedial relief.

d. In considering what remedy is appropriate for an act of retaliation concerning nuclear safety, the Director will also consider the egregiousness of the particular case including the level of management involved in the alleged retaliation and the specificity of the acts of retaliation.

e. When the Director undertakes an investigation of an allegation of DOE contractor retaliation against an employee under part 820, the Director will apprise persons interviewed and interested parties that the investigative activity is being taken pursuant to the nuclear safety procedures of part 820 and not pursuant to the procedures of part 708.

[FR Doc. 2016–19103 Filed 8–11–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2014–1068; Airspace Docket No. 14–AWP–12]

Proposed Amendment of Class E Airspace, Kahului, HI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to modify Class E airspace designated as an extension to a Class C surface area, and modify Class E airspace extending upward from 700 feet above the surface at Kahului Airport, Kahului, HI. Due to changes to the available instrument flight procedures since the last review and advances in Global Positioning System (GPS) mapping accuracy, the FAA found airspace modifications are necessary to ensure the safety and management of Instrument Flight Rules (IFR) operations at the airport with a minimum amount of airspace restriction.

DATES: Comments must be received on or before September 26, 2016.

ADDRESSES: FAA Order 7400.9Z, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/*. For further information, you can contact the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE., West Bldg. Ground Floor Rm. W12–140, Washington, DC 20590; Telephone: 1–800–647–5527, or 202–366–9826. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.9Z at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal-regulations/ibr_locations.html*.

FAA Order 7400.9, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Tom Clark, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA 98057; telephone (425) 203–4511.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part, A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend Class E airspace at Kahului Airport, Kahului, HI.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. FAA–2014–1068; Airspace Docket No. 14–AWP–12." The postcard will be date/time stamped and returned to the commenter.

Availability of NPRMs

An electronic copy of this document and other recently published rulemaking documents may be accessed and downloaded through the Internet at *http://www.regulations.gov*.

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 1601 Lind Avenue SW., Renton, WA 98057.

Availability and Summary of Documents Proposed for Incorporation by Reference

This document proposes to amend FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015. FAA Order 7400.9Z is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.9Z lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) Part 71 to modify the Kahului Airport, Kahului, HI, Class E airspace area designated as an extension to a Class C surface area. The current Class E surface area airspace extension to the north is not required and to the south is longer than required to support IFR operations to/from the airport. The proposed Class E surface airspace includes that area within 3 miles each side of the airport 203° bearing extending from the airport 5-mile radius to 7 miles southwest of the airport.

This proposal would also modify the Class E airspace area extending upward from 700 feet above the surface by excluding that area extending beyond 12 miles from the coast, and would slightly expand the airspace northeast of the airport to within 3.6 miles each side of the 038° bearing from the airport extending from the 5-mile radius to 11.7 miles northeast of the airport. The airspace area would otherwise remain the same, except as noted above. The expanded Class E airspace area is necessary to contain IFR arrival operations descending below 1,500 feet above the surface, and IFR departure operations below 1,200 feet above the surface.

This proposal would also remove reference to the Maui VORTAC from the airspace legal descriptions for the Class E3 airspace area designated as an extension to the Class C surface area, and the Class E5 airspace area extending upward from 700 feet above the surface. Changes to the available instrument flight procedures since the last review, advances in GPS mapping accuracy, and a reliance on precise geographic coordinates to define airport and airspace reference points have made the proposed airspace redesign necessary for the safety and management of Instrument Flight Rules (IFR) operations.

Class E airspace designations are published in paragraphs 6003, and 6005, respectively, of FAA Order 7400.9Z, dated August 6, 2015, and effective September 15, 2015, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, "Environmental Impacts: Policies and Procedures" prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015, is amended as follows:

Paragraph 6003 Class E Airspace Areas Designated as an Extension to a Class C Surface Area.

* * * * *

AWP HI E3 Kahului, HI [Modified]

Kahului Airport, HI

(Lat. 20°53′55″ N., long. 156°25′50″ W.)

That airspace extending upward from the surface within 3 miles each side of the Kahului Airport 203° bearing extending from the 5-mile radius of the airport to 7 miles southwest of the airport. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Pacific Chart Supplement.

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AWP HI E5 Kahului, HI [Modified]

Kahului Airport, HI

(Lat. 20°53′55″ N., long. 156°25′50″ W.)

That airspace extending upward from 700 feet above the surface within a 5-mile radius of Kahului Airport, and within 3.6 miles each side of the airport 038° bearing extending from the 5-mile radius of the airport to 11.7 miles northeast of the airport, and within 2 miles each side of the airport 065° bearing extending from the 5-mile radius of the airport to 10 miles northeast of the airport, and within 3 miles each side of the airport 203° bearing extending from the 5-mile radius of the airport to 10.3 miles southwest of the airport, and within the area bounded by the airport 318° bearing clockwise to the airport 013° bearing extending from the 5-mile radius of the airport to 8.5-miles northeast of the airport, excluding that airspace beyond 12 miles from the coast.

Issued in Seattle, Washington, on August 1, 2016.

Tracey Johnson,

Manager, Operations Support Group, Western Service Center.

[FR Doc. 2016–19004 Filed 8–11–16; 8:45 am]

BILLING CODE 4910–13–P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 3

RIN 3038–AE49

Chief Compliance Officer Annual Report Requirements for Futures Commission Merchants, Swap Dealers, and Major Swap Participants; Amendments to Filing Dates

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Commodity Futures Trading Commission ("Commission" or "CFTC") is proposing to amend certain provisions of its regulations concerning Chief Compliance Officers ("Proposal"). The regulation that is the subject of the Proposal addresses chief compliance officers ("CCOs") of futures commission merchants ("FCMs"), swap dealers ("SDs"), and major swap participants ("MSPs") (collectively, "Registrants"). The proposed amendments would: Codify existing no-action relief regarding the timing of when a Registrant must furnish its CCO annual report to the Commission; clarify filing requirements for Registrants located in a jurisdiction for which the Commission has issued a comparability determination; and delegate to the Director of the Division of Swap Dealer and Intermediary Oversight ("DSIO") authority to grant extensions to the CCO annual report filing deadline.

DATES: Comments must be received on or before September 12, 2016.

ADDRESSES: You may submit comments, identified by RIN 3038–AE49, by any of the following methods:

- *CFTC Web site: http://comments.cftc.gov.* Follow the instructions for submitting comments through the Comments Online process on the Web site.
- *Mail:* Send to Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581.
- *Hand Delivery/Courier:* Same as Mail, above.

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Please submit your comments using only one of these methods.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *http://www.cftc.gov.* You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that is exempt from disclosure under the Freedom of Information Act ("FOIA"),[1] a petition for confidential treatment of the exempt information may be submitted according to the procedures set forth in § 145.9 of the Commission's regulations.[2]

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from *www.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the rulemaking will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the FOIA.

FOR FURTHER INFORMATION CONTACT: Eileen Flaherty, Director, 202–418–5326, *eflaherty@cftc.gov;* Erik Remmler, Deputy Director, 202–418–7630, *eremmler@cftc.gov;* Laura Gardy, Associate Director, 202–418–7645, *lgardy@cftc.gov;* or Pamela M. Geraghty, Special Counsel, 202–418–5634, *pgeraghty@cftc.gov,* Division of Swap Dealer and Intermediary Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

I. Background

A. Commission Requirements for Submission of CCO Annual Reports

Section 4s(k)(3) of the Commodity Exchange Act ("CEA") requires CCOs for SDs and MSPs, in accordance with rules prescribed by the Commission, to prepare and sign an annual report ("CCO Annual Report") describing, among other things, the SD's or MSP's compliance with the CEA and CFTC regulations.[3] CEA section 4s(k)(3)(B) requires the CCO Annual Report to accompany each appropriate financial report of the SD or MSP required to be furnished to the Commission.[4] CEA section 4d(d) requires CCOs of FCMs to "perform such duties and responsibilities" as are established by Commission regulation or rules of a registered futures association.[5]

Regulations 3.3(e) and (f) codify the duty to prepare and furnish to the Commission a CCO Annual Report for all Registrants.[6] Regulation 3.3(e) requires the CCO Annual Report to cover the most recently completed fiscal year of the Registrant and specifies certain reporting elements for Registrants in describing their compliance with the CEA and Commission regulations. Regulation 3.3(f)(1) requires the furnishing of the CCO Annual Report to the board or senior officer prior to its submission to the Commission. Regulation 3.3(f)(2) currently requires the CCO Annual Report to be furnished to the Commission electronically not more than 60 days after a Registrant's fiscal year-end.

B. Regulation 3.3(f)(2) Implementation Experience

Since the adoption of the 60-day filing requirement, DSIO has continuously provided no-action relief for CCO Annual Reports submitted to the Commission within 90 days of a Registrant's fiscal year-end.[7] The no-action letter currently in effect, CFTC Staff Letter No. 15–15, responds to a request for relief on behalf of FCM and SD firms, which stated that having an additional 30 days to file the CCO Annual Report allows each Registrant to conduct a more substantive and complete review of its compliance program.[8]

Recently, the U.S. Securities and Exchange Commission ("SEC") adopted final rules corresponding to Regulation 3.3, and implementing a provision of Title VII of the Dodd-Frank Act the text of which is effectively identical to CEA section 4s(k)(3)(B).[9] The SEC's corresponding rule requires that the equivalent chief compliance officer annual report for security-based swap dealers and major security-based swap participants be submitted to the SEC within 30 days following the deadline for filing each entity's annual financial report.[10]

C. Application of Regulation 3.3(f)(2) to Entities Located in Certain Non-U.S. Jurisdictions

In December 2013, the Commission issued comparability determinations deeming an SD or MSP located in Canada, the European Union, Hong Kong, Japan, or Switzerland ("Substituted Compliance Registrants") to be in compliance with Regulation 3.3(e) if it complies with the applicable corresponding regulation in its home jurisdiction.[11] Specifically, a Substituted Compliance Registrant may elect to furnish the Commission with the comparable annual reporting information (hereinafter, "Comparable Annual Report") specified under the standards of its home jurisdiction. However, the Commission did not provide a comparability determination with respect to Regulation 3.3(f) regarding the timing of when the

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[1] 5 U.S.C. 552.

[2] 17 CFR 145.9. The Commission's regulations are found at 17 CFR Chapter I and can be accessed through the Commission's Web site at *www.cftc.gov.*

[3] 7 U.S.C. 6s(k)(3)(A)(i). The CEA can be accessed through the Commission's Web site.

[4] 7 U.S.C. 6s(k)(3)(B)(i).

[5] 7 U.S.C. 6d(d).

[6] 17 CFR 3.3(e) and (f).

[7] *See* CFTC Letter No. 13–84, Time-Limited No-Action Relief for Futures Commission Merchants, Swap Dealers, and Major Swap Participants from Compliance with the Timing Requirements of Commission Regulation 3.3(f)(2) Relating to Annual Reports by Chief Compliance Officers (Dec. 30, 2013), *available at: http://www.cftc.gov/idc/groups/public/@lrlettergeneral/documents/letter/13-84.pdf;* CFTC Letter No. 14–154, Time-Limited No-Action Relief for Futures Commission Merchants, Swap Dealers, and Major Swap Participants from Compliance with the Timing Requirements of Commission Regulation 3.3(f)(2) Relating to Annual Reports by Chief Compliance Officers (Dec. 22, 2014), *available at: http://www.cftc.gov/idc/groups/public/@lrlettergeneral/documents/letter/14-154.pdf;* and CFTC Letter No. 15–15, No-Action Relief for Futures Commission Merchants, Swap Dealers, and Major Swap Participants from Compliance with the Timing Requirements of Commission Regulation 3.3(f)(2) Relating to Annual Reports by Chief Compliance Officers (Mar. 27, 2015), *available at: http://www.cftc.gov/idc/groups/public/@lrlettergeneral/documents/letter/15-15.pdf* ("CFTC Staff Letter No. 15–15").

[8] FIA and ISDA Letter, Request for no-action relief concerning certain requirements of CFTC Rule 3.3 relating to the timing of the Annual Report (Mar. 10, 2015) (on file with the CFTC, available for inspection and copying).

[9] Business Conduct Standards for Security-Based Swap Dealers and Major Security-Based Swap Participants, 81 FR 29959 (May 13, 2016).

[10] *See id.* at 30150.

[11] *See* Comparability Determination for Canada: Certain Entity-Level Requirements, 78 FR 78839, 78843 (Dec. 27, 2013); Comparability Determination for the European Union: Certain Entity-Level Requirements, 78 FR 78923, 78928 (Dec. 27, 2013); Comparability Determination for Hong Kong: Certain Entity-Level Requirements, 78 FR 78852, 78856 (Dec. 27, 2013); Comparability Determination for Japan: Certain Entity-Level Requirements, 78 FR 78910, 78915 (Dec. 27, 2013); Comparability Determination for Switzerland: Certain Entity-Level Requirements, 78 FR 78899, 78903 (Dec. 27, 2013). It should be noted that while Australia was granted a determination of comparability for some entity-level requirements, it was not granted a determination of comparability with respect to the requirements of Regulation 3.3(e). *See* Comparability Determination for Australia: Certain Entity-Level Requirements, 78 FR 78864, 78869 (Dec. 27, 2013).

Comparable Annual Report must be furnished to the CFTC.[12]

II. The Proposal

A Proposed Amendments to Regulation 3.3(f)(2)

The Commission is proposing to codify the current no-action relief by amending Regulation 3.3(f)(2). The amendments would permit an FCM to furnish its CCO Annual Report to the Commission not more than 30 days after submission of the Form 1–FR–FCM[13] or Financial Operational Combined Uniform Single Report ("FOCUS Report"). The Proposal would also permit an SD or MSP to furnish its CCO Annual Report to the Commission not more than 90 days after its fiscal year-end until such time as the Commission adopts and implements rules establishing the time for filing the annual financial condition report required under CEA section 4s(f). The Commission has proposed, but not yet adopted, a financial condition report requirement comprised of an annual audited financial report for SDs and MSPs.[14] Once the Commission adopts and implements a financial condition report rule, like FCMs, an SD or MSP will have up to 30 days after the submission of its annual financial condition report to submit the CCO Annual Report to the Commission.

Regulation 3.3(e) requires a broad and detailed assessment of each Registrant's compliance program over the preceding year as well as a discussion of planned changes and remedial steps to be taken for non-compliance matters. The Commission believes that providing up to 30 days after a Registrant's applicable financial reports are due would provide Registrants an appropriate amount of time to complete the in-depth review and analyses required by Regulation 3.3(e). As a policy matter, the Commission recognizes that the periodic self-evaluation that underlies each CCO Annual Report is a critical step in promoting an active and robust compliance culture within firms.

In codifying the relief provided in CFTC Staff Letter No. 15–15, the Commission is clarifying that the statutory requirement for an SD or MSP's CCO Annual Report to "accompany each appropriate financial report" allows for the CCO Annual Report to be furnished to the Commission not more than 30 days after the submission of a Registrant's annual financial report.[15] The Commission recognizes the separate and distinct nature and purposes of the two reports, and believes that allowing Registrants to submit their CCO Annual Reports not more than 30 days after their financial reports are due satisfies the statutory requirement that the CCO Annual Report "accompany" the other financial report. This is also consistent with the SEC's approach in its corresponding rule for delivery of chief compliance officer annual reports by security-based swap dealers and major security-based swap participants.[16]

B. Registrants Located in Substituted Compliance Jurisdictions

The Commission is also proposing to amend Regulation 3.3(f) to address the timing of the filing requirement for Comparable Annual Reports. If the requirements of the Substituted Compliance Registrant's home jurisdiction identify a specific date by which the Comparable Annual Reports must be completed, then the Commission is proposing that Comparable Annual Reports may be furnished to the Commission electronically up to 15 days after the date on which the Comparable Annual Report must be completed.[17] The additional 15 days would allow time for translation of the report text into English. If the Substituted Compliance Registrant's home jurisdiction does not establish a specifically identifiable completion date, then the Substituted Compliance Registrant must comply with the standard time frames provided in Regulation 3.3(f), as amended. A specifically identifiable completion date would be a date that can be clearly identified such as a specific calendar date or a set number of days after the Substituted Compliance Registrant's fiscal year-end. A home jurisdiction requirement to complete the Comparable Annual Report only if some event occurs or upon request, or which does not specify a deadline, is not considered comparable to the Commission's annual delivery requirement.

C. Proposed Amendments Regarding a Delegation From the Commission to the Division

Pursuant to Regulation 3.3(f)(5), Registrants may request from the Commission an extension of time to furnish their CCO Annual Reports if the failure to timely furnish the report could not be avoided absent "unreasonable effort or expense." The rule provides the Commission with discretion in granting such extensions. To expedite review and consideration of requests for extensions, the Commission is proposing to delegate to the Director of DSIO, or such other employee(s) that the Director may designate, the authority to grant extensions of time subject to the same standard set forth in Regulation 3.3(f)(5). The Commission notes that the exercise of such delegated authority would need to be consistent with Regulation 3.3(f)(5) and therefore would be limited to unique facts and circumstances that clearly demonstrate that the inability to timely furnish the report to the Commission could not have been eliminated absent unreasonable effort or expense. The Commission believes that such delegation is prudent given that the decision to provide an extension requires consideration of specific facts and circumstances and often this consideration needs to occur within a relatively short period of time. As is the case with existing delegations to staff, the Commission would continue to reserve the right to perform the functions described in Regulation 3.3(f)(5) itself at any time.[18]

The Commission requests comment on the appropriateness of the proposed delegation and whether additional procedural detail is necessary.

D. Request for Comment

The Commission seeks comments regarding the following matters:

- Given the current filing requirements for the Form 1–FR–FCM and FOCUS Reports, and the anticipated filing requirements for the financial condition report, is it appropriate to permit FCMs, SDs, and MSPs an additional 30-days to furnish their CCO Annual Report to the Commission? Are there any practical or policy reasons for not permitting the additional 30 days?

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[12] *See* note 11, *supra.*

[13] The proposed amendment also makes a technical correction in Regulation 3.3(f)(2) by correcting the cross reference to the Commission regulation that requires the filing of Form 1–FR–FCM to Regulation 1.10(b)(1)(ii).

[14] *See* Capital Requirements of Swap Dealers and Major Swap Participants, 76 FR 27802, 27838 (proposed May 12, 2011).

[15] The Proposal would remove the obligation of Registrants to file their CCO Annual Reports "simultaneously" with the applicable FCM financial report or financial condition report.

[16] In the adopting release, the SEC addresses the statutory language that links the filing of the CCO Annual Report with the filing of appropriate financial reports by stating, "The Commission is interpreting 'accompany' in Section 15F(k)(3)(B)(i) to mean follow within 30 days." 81 FR 29959, 30059, n.1238.

[17] While each of the jurisdictions that have been granted a comparability determination with respect to Regulation 3.3(e) requires Substituted Compliance Registrants to produce and complete comparable annual reporting information, there is variation among the foreign jurisdictions as to whether and/or when a Comparable Annual Report must be furnished to the home regulator. Therefore, the Commission is using the date on which the Comparable Annual Report must be completed as the benchmark for determining when the Comparable Annual Report must be furnished to the Commission.

[18] In addition, notwithstanding any such delegation, in any case in which a Commission employee delegated authority under this section believes it is appropriate, the employee may submit the question to the Commission for its consideration.

- Does codifying the relief granted in CFTC Staff Letter No. 15–15 sufficiently address Registrants' concerns?
- Should the Commission provide any further clarification of the requirements of Regulation 3.3(f) as they apply to entities located in jurisdictions for which comparability determinations have been issued?

III. Related Matters

A. Regulatory Flexibility Act

The Regulatory Flexibility Act[19] ("RFA") requires that agencies consider whether the rules they propose will have a significant economic impact on a substantial number of small entities and, if so, provide a regulatory flexibility analysis reflecting the impact. Section 3.3(f)(2), as proposed, amends the filing deadline for CCO Annual Reports of FCMs, SDs, and MSPs and clarifies the filing deadline for Comparable Annual Reports. The proposed amendments would affect FCMs, SDs, and MSPs that are required to be registered with the Commission. The Commission has previously established certain definitions of "small entities" to be used in evaluating the impact of its regulations on small entities in accordance with the RFA, and has previously determined that FCMs, SDs, and MSPs are not small entities for purposes of the RFA.[20] Therefore, the Commission believes that the amendments to Regulation 3.3 would not have a significant economic impact on a substantial number of small entities. Accordingly, the Chairman, on behalf of the Commission, hereby certifies, pursuant to 5 U.S.C. 605(b), that the proposed amendments will not have a significant economic impact on a substantial number of small entities.

B. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 ("PRA")[21] provides that a federal agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number issued by the Office of Management and Budget ("OMB"). The collection of information related to this proposed rule is OMB control number 3038–0080—Annual Report for Chief Compliance Officer of Registrants. The Commission believes that this proposed rule will not impose any new information collection requirements that require approval of OMB under the PRA. As a general matter, the proposed rule would allow Registrants up to 90 days after the end of their fiscal years, and certain Substituted Compliance Registrants with up to 15 days after the date on which the Comparable Annual Report must be completed under the requirements of their home jurisdiction, to file the CCO Annual Report and Comparable Annual Reports, respectively. As such, this proposed rule does not, by itself, impose any new burden or any new information collection requirements in addition to those that already exist in connection with the preparation and delivery of the CCO Annual Report pursuant to part 3 of the Commission's regulations.

C. Cost-Benefit Considerations

1. Background

As discussed above, the Commission is proposing amendments to the filing requirements for CCO Annual Reports in Regulation 3.3 that would: (1) Increase the amount of time registrants have to file their CCO Annual Reports with the Commission; and (2) clarify the filing requirements for Comparable Annual Reports. The baseline for this cost and benefit consideration is existing Regulation 3.3. Although CFTC Staff Letter No. 15–15, as discussed above, currently offers no-action relief that is substantially similar to the relief that the proposed amendments would grant Registrants, as a no-action letter, it only represents the position of the issuing Division or Office and cannot bind the Commission or other Commission staff.[22] Consequently, the Commission believes that CFTC Staff Letter No. 15–15 should not set or affect the baseline against which the Commission considers the costs and benefits of the proposal.

2. Costs

The Commission received no comments during the rulemaking process for Regulation 3.3 regarding costs associated with the timing of the filing deadline for the CCO Annual Report. The proposed amendment does not change the report contents or require any additional actions to be taken by Registrants. The additional 30 days (or up to 15 days after the date on which a Comparable Annual Report must be completed under applicable home jurisdiction standards that allow more time) provided by the proposal lengthens the time before senior management or the board of the Registrants and the Commission may receive the CCO Annual Reports. The additional time to furnish the reports should not materially impact regulatory oversight given that the purpose of the reports is to provide a status update for the Registrant's compliance activities over the course of the preceding fiscal year and planned changes for the coming year. The reports generally do not serve to address crisis situations for which immediacy is critical. Therefore, the additional time allowed will not materially impact the usefulness of the information in the reports.[23] The Commission has no other information available to it that would indicate that changing the filing deadline would measurably change the cost to prepare the CCO Annual Reports. Accordingly, the Commission preliminarily believes that the proposal would not impose any additional costs on any other market participants, the markets themselves, or the general public. The Commission invites comment regarding the nature of, and the extent to which, costs associated with the CCO Annual Reports could change as a result of the adoption of the proposal and, to the extent they can be quantified, monetary and other numerical estimates thereof.

3. Benefits

The Commission believes that the proposal would provide relief for Registrants from time pressures in preparing and filing their CCO Annual Reports. The additional time provided will allow Registrants to more carefully complete their internal processes used to develop the broad variety of information needed for the reports resulting in more accurate and complete reports. The Commission invites comment regarding the nature and extent of these and any other benefits that could result from adoption of the proposal—including benefits to other market participants, the market itself, or the general public—and, to the extent they can be quantified, monetary and other numerical estimates thereof.

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[19] 5 U.S.C. 601 *et seq.*

[20] *See* Policy Statement and Establishment of Definitions of "Small Entities" for Purposes of the Regulatory Flexibility Act, 47 FR 18618, 18619 (Apr. 30, 1982) (FCMs); Further Definition of "Swap Dealer," "Security-Based Swap Dealer," "Major Swap Participant," "Major Security-Based Swap Participant" and "Eligible Contract Participant," 77 FR 30596, 30701 (May 23, 2012) (SDs and MSPs).

[21] 44 U.S.C. 3501 *et seq.*

[22] *See* 17 CFR 140.99(a)(2). *See also* CFTC Staff Letter No. 15–15 at 4.

[23] The CCO Annual Report must contain a description of material non-compliance events that occurred over the review period. However, reporting on those events in the CCO Annual Report provides transparency regarding the effectiveness of the implementation of the compliance program over the preceding year for management and the CFTC.

4. Section 15(a) Factors

Section 15(a) of the CEA requires the Commission to consider the costs and benefits of its actions before promulgating a regulation under the CEA or issuing certain orders.[24] Section 15(a) further specifies that the costs and benefits shall be evaluated in light of five broad areas of market and public concern: (1) Protection of market participants and the public; (2) efficiency, competitiveness, and financial integrity of futures markets; (3) price discovery; (4) sound risk management practices; and (5) other public interest considerations. The Commission considers the costs and benefits resulting from its discretionary determinations with respect to the section 15(a) factors.

a. Protection of Market Participants and the Public

The Commission recognizes that there are trade-offs between reducing regulatory burdens and ensuring that the Commission has sufficient, timely information to fulfill its regulatory mission. The proposed amendments to Regulation 3.3 are intended to reduce some of the regulatory burdens on Registrants. While the amendment will delay the time by which the Commission will receive the CCO Annual Reports, the delay is relatively short given that the information in the reports looks back over the entire year-long reporting period and identifies planned improvements for the coming year. Accordingly, the Commission preliminarily believes that the short delay will not affect the protection of market participants and the public.

b. Efficiency, Competitiveness, and Financial Integrity of Markets

The Commission believes that the proposed amendments to Regulation 3.3 could improve allocational efficiency for participants in the market by reducing the burden of preparing the CCO Annual Report in a shorter time-frame, thereby allowing them to allocate compliance resources more efficiently over the report preparation period. The Commission preliminarily believes that the proposed amendments to Regulation 3.3 will not have any market efficiency, competitiveness, or market integrity impacts because the reports address internal compliance programs of each Registrant and are not publicly available.

c. Price Discovery

The Commission preliminarily believes that the proposed amendments to Regulation 3.3 would not impact on price discovery. Given the fact that the proposed amendments affect only the timing of when the CCO Annual Reports are filed with the Commission and the CCO Annual Reports generally would not contain trade information or be available to the public, the proposed amendments would not affect price discovery.

d. Sound Risk Management Practices

The Commission preliminarily believes that the proposed amendments would not have a meaningful effect on the risk management practices of Registrants. While the CCO Annual Reports may discuss certain risk management aspects related to the compliance programs of the Registrants, the proposal would only amend the timing of delivery of the reports to the Commission, not the contents of the reports. As described above under subsection 4.a, the short delay in delivery of the reports provided for by the proposal is not significant given the nature of the information included in the report and allowing additional time to prepare the CCO Annual Reports might allow the Registrants to prepare better reports that more effectively address the information contained therein.

e. Other Public Interest Considerations

The Commission has not identified any other public interest considerations for this rulemaking.

5. Request for Comment

The Commission invites comment on all aspects of its preliminary consideration of the costs and benefits associated with the proposal and the five factors the Commission is required to consider under CEA section 15(a). In addressing these areas and any other aspect of the Commission's preliminary cost-benefit considerations, the Commission encourages commenters to submit any data or other information they may have quantifying and/or qualifying the costs and benefits of the proposal.

List of Subjects in 17 CFR Part 3

Administrative practice and procedure, Brokers, Commodity futures, Major swap participants, Reporting and recordkeeping requirements, Swap dealers.

For the reasons stated in the preamble, the Commodity Futures Trading Commission proposes to amend 17 CFR part 3 as follows:

PART 3—REGISTRATION

■ 1. The authority citation for part 3 is revised to read as follows:

Authority: 5 U.S.C. 552, 552b; 7 U.S.C. 1a, 2, 6a, 6b, 6b–1, 6c, 6d, 6e, 6f, 6g, 6h, 6*i*, 6k, 6m, 6n, 6*o*, 6p, 6s, 8, 9, 9a, 12, 12a, 13b, 13c, 16a, 18, 19, 21, 23, as amended by Title VII of the Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. 111–203, 124 Stat. 1376 (Jul. 21, 2010).

■ 2. Amend § 3.3 as follows:
■ a. Revise paragraph (f)(2); and
■ b. Add paragraph (h).

The revision and addition to read as follows:

§ 3.3 Chief compliance officer.

* * * * *

(f) * * *

(2)(i) Except as provided in paragraph (f)(2)(ii) of this section, the annual report shall be furnished electronically to the Commission not more than 30 days after the submission of Form 1–FR–FCM, as required under § 1.10(b)(1)(ii) of this chapter, the Financial and Operational Combined Uniform Single Report, as required under § 1.10(h) of this chapter, or the financial condition report, as required under section 4s(f) of the Act, as applicable. Until such time as the Commission adopts and implements a regulation establishing the time for filing the financial condition report, a swap dealer or major swap participant shall furnish the annual report electronically to the Commission not more than 90 days after the end of its fiscal year.

(ii) The annual report of a swap dealer or major swap participant that is eligible to comply with a substituted compliance regime for paragraph (e) of this section pursuant to a comparability determination of the Commission may be furnished to the Commission electronically up to 15 days after the date on which the comparable annual report must be completed under the requirements of the applicable substituted compliance regime. If the substituted compliance regime does not specify a date by which the comparable annual report must be completed, then the annual report shall be furnished to the Commission by the date specified in paragraph (f)(2)(i) of this section.

* * * * *

(h) *Delegation of Authority.* The Commission hereby delegates to the Director of the Division of Swap Dealer and Intermediary Oversight, or such other employee or employees as the Director may designate from time to time, the authority to grant extensions of time, as set forth in paragraph (f)(5) of this section. Notwithstanding such delegation, in any case in which a Commission employee delegated authority under this paragraph believes it appropriate, he or she may submit to the Commission for its consideration the question of whether an extension of time should be granted. The delegation of authority in this paragraph shall not prohibit the Commission, at its election, from exercising the authority set forth in paragraph (f)(5) of this section.

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[24] 7 U.S.C. 19(a).

Issued in Washington, DC, on August 8, 2016, by the Commission.

Christopher J. Kirkpatrick,

Secretary of the Commission.

Note: The following appendix will not appear in the Code of Federal Regulations.

Appendix to Chief Compliance Officer Annual Report Requirements for Futures Commission Merchants, Swap Dealers, and Major Swap Participants; Amendments to Filing Dates—Commission Voting Summary

On this matter, Chairman Massad and Commissioners Bowen and Giancarlo voted in the affirmative. No Commissioner voted in the negative.

[FR Doc. 2016–19231 Filed 8–11–16; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF THE INTERIOR

Bureau of Safety and Environmental Enforcement

30 CFR Part 250

[Docket ID: BSEE–2016–0004; 16XE1700DX EEEE500000 EX1SF0000.DAQ000]

RIN 1014–AA32

Oil and Gas and Sulfur Operations in the Outer Continental Shelf—Decommissioning Costs for Pipelines

AGENCY: Bureau of Safety and Environmental Enforcement, Department of the Interior.

ACTION: Proposed rule.

SUMMARY: The Bureau of Safety and Environmental Enforcement (BSEE) proposes to amend the regulations requiring lessees and owners of operating rights to submit summaries of actual decommissioning expenditures incurred for certain decommissioning activities related to oil and gas and sulfur operations on the Outer Continental Shelf (OCS). The proposed rule would expand the scope of the current regulations to require lessees, owners of operating rights, and right-of-way (ROW) holders to submit summaries of actual expenditures incurred for pipeline decommissioning activities.

DATES: Submit comments by September 12, 2016. BSEE may not fully consider comments received after this date. You may submit comments to the Office of Management and Budget (OMB) on the information collection burden in this proposed rule by September 12, 2016.

ADDRESSES: You may submit comments on this proposed rulemaking by any of the following methods. Please use the Regulation Identifier Number (RIN) 1014–AA32 as an identifier in your message. BSEE may post all submitted comments on a public Web site.

1. Submit comments electronically via the Federal eRulemaking Portal: *http://www.regulations.gov.* In the entry titled "Enter Keyword or ID," enter BSEE–2016–0004, then click "Search." Follow the instructions to submit public comments and view supporting and related materials available for this proposed rulemaking.

2. Mail or hand-carry comments to the Department of the Interior (DOI); Bureau of Safety and Environmental Enforcement; Attention: Regulations and Standards Branch; 45600 Woodland Road, Sterling, VA 20166, VAE–ORP. Please reference "Decommissioning Costs for Pipelines, 1014–AA32" in your comments and include your name and return address.

3. Comments on the information collection contained in this proposed rule should be submitted separately from those on the substance of the proposed rule. Send comments on the information collection burden in this proposed rule to: OMB, Interior Desk Officer 1014–AA32, 202–395–5806 (fax); or email: *OIRA_submission@omb.eop.gov.* Please send a copy of your comments to BSEE using one of the methods previously described.

FOR FURTHER INFORMATION CONTACT: Betty Cox, Regulatory Analyst, Regulations and Standards Branch, *Betty.Cox@bsee.gov,* (703) 787–1616.

SUPPLEMENTARY INFORMATION:

BSEE's Functions and Authority

BSEE promotes safety, protects the environment, and conserves natural resources through vigorous regulatory oversight and enforcement of certain activities on the OCS. BSEE derives its authority primarily from the Outer Continental Shelf Lands Act (OCSLA), 43 U.S.C. 1331–1356a. Congress enacted OCSLA in 1953, codifying Federal control over the OCS and authorizing the Secretary of the Interior (Secretary) to regulate oil and natural gas exploration, development, and production operations on the OCS. The Secretary has authorized BSEE to perform certain of these functions, including overseeing decommissioning. (*See* 30 CFR 250.101; 30 CFR part 250, subpart Q.) To carry out its responsibilities, BSEE regulates exploration, development, and production of oil and natural gas to enhance safety and environmental protection in a way that reflects advancements in technology and new information. BSEE also conducts onsite inspections to ensure compliance with regulations, lease terms, and approved plans or permits. Detailed information concerning BSEE's regulations and guidance for the offshore industry may be found on BSEE's Web site at: *www.bsee.gov/Regulations-and-Guidance/index.*

Public Participation and Availability of Comments

BSEE encourages you to participate in this proposed rulemaking by submitting written comments, as discussed in the **ADDRESSES** and **DATES** sections of this proposed rule. This proposed rule provides 30 days for public comment for the following reasons. The need for submission of actual decommissioning cost information for plugging wells, removing platforms, and clearing of sites was explained in a proposed rule published on May 27, 2009 (74 FR 25177) and a final rule published on December 4, 2015 (80 FR75806). That final rule addressed and responded to all of the relevant comments submitted on the proposed rule. This proposed rule would extend the existing requirements for submitting summaries of actual decommissioning costs (30 CFR 250.1704(i) and (j)) to pipelines. The reasons for this proposed rule, as discussed in the Background and Purpose of Proposed Amendment sections of this notice are effectively the same for pipelines as the reasons discussed in the December 4, 2016 rule for the reporting of decommissioning costs for other facilities. BSEE does not expect that public comments on this proposed rule are likely to raise any significant issues that were not raised in the earlier decommissioning cost reporting rulemaking. Moreover, the affected stakeholders in the oil and gas industry are already familiar with the terms and requirements of the existing decommissioning cost reporting rule, which would apply without change to pipelines under this proposed rule. Accordingly, BSEE has determined that 30 days provides a reasonable and adequate opportunity for the public to comment on this proposed rule.

Before including your address, phone number, email address, or other personal identifying information in your comment on this proposed rule, however, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Background

Among its responsibilities, BSEE regulates certain types of oil and gas pipelines used on the OCS. (*See* 30 CFR 250.1000–250.1019). In general, BSEE regulates pipelines or pipeline segments on the OCS that are operated by oil and gas producers, as opposed to pipelines operated by transporters. Specifically, BSEE regulates producer-operated pipelines that: (1) Extend upstream (generally seaward) from each point on the OCS at which operating responsibility transfers from a producing operator to a transporting operator; (2) extend upstream (generally seaward) from the last valve (including associated safety equipment) on the last OCS production facility and that do not connect to a transporter-operated pipeline on the OCS before crossing into State waters; or (3) connect production facilities on the OCS. (*See* § 250.1001.) BSEE also regulates transporter-operated pipelines that DOI and the U.S. Department of Transportation (DOT) have agreed are to be regulated as DOI pipelines as well as all other OCS pipelines not subject to DOT regulation.[1] (*See id.*)

Pipelines regulated by BSEE generally fall within two categories: (1) "lease term" pipelines (*i.e.*, pipelines owned and operated by a lessee or operator and located entirely within the boundaries of a single lease, unitized leases, or the contiguous leases of that lessee or operator); or (2) ROW pipelines (*i.e.*, OCS pipelines owned and operated by an entity other than the lessee or operator of the lease(s), unit, or contiguous leases in which the pipeline is contained, as well as pipelines that cross unleased areas).[2] Among other things, BSEE approves the installation, modification, and decommissioning of all lease term and ROW pipelines, and the modification or relinquishment of all pipeline ROW grants on the OCS. BSEE's regulations for decommissioning pipelines are found at 30 CFR 250.1700 through 250.1704 and 250.1750 through 250.1754.

As of August 1, 2016, BSEE regulates 4,842 active pipeline segments[3] (totaling approximately 20,837 miles) and 1,553 out-of-service pipeline segments (totaling approximately 2,249 miles). In addition, BSEE has regulatory authority over 8,832 decommissioned pipeline segments, as well as 825 pipeline segments that have been approved for decommissioning.

BSEE's requirements for decommissioning a pipeline are found at §§ 250.1750–250.1754. Pursuant to § 250.1751, requirements for decommissioning a pipeline in place include: pigging (to remove any residual hydrocarbons from the pipeline), unless the Regional Supervisor determines that pigging is not practical; flushing and filling the pipeline with seawater; cutting and plugging the ends of the pipeline; and burying the ends at least 3 feet below the seafloor or covering the ends with protective concrete mats, if required by the Regional Supervisor. Section 250.1751(g) also requires removal of all valves and other fittings that could unduly interfere with other uses of the OCS.

In addition, under § 250.1754, BSEE has the authority to require that lessees, owners of operating rights, and ROW holders remove pipelines previously decommissioned in place if and when the Regional Supervisor determines that the pipeline is an obstruction.

BSEE's requirements for decommissioning by removing all or part of a pipeline are found at § 250.1752 and include, in part, pigging and flushing the pipeline (unless the Regional Supervisor determines that pigging is not practical) before removal.

Purpose of Proposed Amendment

In 2009, BSEE's predecessor agency, the Minerals Management Service (MMS), proposed new reporting requirements related to lease term pipelines when MMS approves a lease assignment. (*See* 74 FR 25177 (May 27, 2009).) MMS also proposed to require the submission of information on expenditures for decommissioning of wells, platforms and other facilities and for site clearance. (*See id.*)

In a final rule published on December 4, 2015, BSEE amended its regulations to require lessees and owners of operating rights to submit summaries of actual decommissioning expenditures for certain required decommissioning activities within 120 days after completion of each such activity. (*See* 80 FR 75806.) Specifically, the final rule required reporting of summaries of expenditures for plugging wells, removing platforms and other facilities, and clearing obstructions from sites. In addition, the final rule authorized BSEE to require additional supporting information regarding specific decommissioning costs on a case-by-case basis. The final rule was codified at 30 CFR 250.1704(h) and (i).

Effective July 28, 2016, BSEE's Well Control final rule revised paragraph (g) in § 250.1704, added a new paragraph (h), and redesignated existing paragraphs (h) and (i) as paragraphs (i) and (j), respectively. (*See* 81 FR 25888 (April 29, 2016).) The Well Control rule did not, however, affect the substance of those decommissioning cost reporting provisions.

On April 27, 2016, BSEE issued a Notice to Lessees and Operators (NTL), No. 2016–N03, *Reporting Requirements for Decommissioning Expenditures on the OCS,* providing guidance and clarification regarding the submission of the decommissioning cost summaries required by § 250.1704(i).

BSEE did not include reporting of expenditures for pipeline decommissioning in the December 2015 final rule because the 2009 proposed rule did not expressly refer to pipeline decommissioning expenditures. BSEE has determined, however, that accurate information about expenditures incurred for pipeline decommissioning activities is needed to better estimate future decommissioning costs for those activities.

As BSEE explained in the December 2015 final rule, with regard to expenditures for other types of decommissioning activities under § 250.1704(i), summaries of actual decommissioning expenditures will help BSEE better estimate future decommissioning costs. (*See* 80 FR 75806.) For the same reason, summaries of actual pipeline decommissioning expenditures will help BSEE better estimate future decommissioning costs. In addition, BSEE will share its decommissioning cost estimates with the Bureau of Ocean Energy Management (BOEM) for use in setting necessary financial assurance levels to (1) minimize the possibility that the government will incur future financial liability for decommissioning pipelines where the responsible party has failed to carry out the required decommissioning; and (2) enhance the accuracy of financial assurance requirements necessary to cover future decommissioning liabilities.

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[1] BSEE-regulated pipelines are also referred to as "DOI pipelines." *See* 30 CFR 250.1001. Pipelines subject to DOT regulations are commonly referred to as "DOT pipelines," *see id.*, and are regulated by the DOT Pipeline and Hazardous Materials Safety Administration (PHMSA).

[2] ROW pipelines also include all DOI pipelines not defined as lease term pipelines. *See* 30 CFR 250.1001 for definitions of lease term pipelines and ROW pipelines.

[3] BSEE assigns pipeline segment numbers as specific pipeline identifiers.

Accordingly, BSEE proposes to expand the scope of § 250.1704(i) to require that lessees, owners of operating rights, and pipeline ROW holders submit certified summaries of actual expenditures for decommissioning of pipelines.[4] This proposal would also authorize Regional Supervisors, under § 250.1704(j), to require the submission of additional information, on a case-by-case basis, to support summaries of pipeline decommissioning expenditures submitted under § 250.1704(i). This proposal rule would not otherwise revise the existing decommissioning cost reporting provisions.

Procedural Matters

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order (E.O.) 12866 provides that OMB, Office of Information and Regulatory Affairs (OIRA), will review all significant rules. BSEE has determined that this proposed rule would not be a significant regulatory action as defined by section 3(f) of E.O. 12866 because:

—It is not expected to have an annual effect on the economy of $100 million or more;

—It would not adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

—It would not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

—It would not materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights or obligations of their recipients; and

—It would not raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in E.O. 12866.

Accordingly, BSEE has not prepared an economic analysis beyond the analysis required under the Paperwork Reduction Act, and OIRA has not reviewed this proposed rule.

E.O. 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the Nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. E.O. 13563 directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. It also emphasizes that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. BSEE developed this proposed rule in a manner consistent with these requirements.

Regulatory Flexibility Act (RFA)

BSEE certifies that this proposed rule would not have a significant economic effect on a substantial number of small entities under the RFA (5 U.S.C. 601 *et seq.*). This proposed rule would potentially affect offshore lessees, owners of operating rights and other operators, and pipeline ROW holders who perform decommissioning activities under 30 CFR part 250, subpart Q. In the December 2015 final rule, using the Small Business Administration's North American Industry Classification System (NAICS) codes 211111 (Crude Petroleum and Natural Gas Extraction) and 213111 (Drilling Oil and Gas Wells), we estimated that a substantial number, about 90 of the 130 active companies potentially affected by that rule (*i.e.,* lessees and operators), would be considered small entities. (*See* 80 FR 75808.) However, we concluded that the final rule would not have a significant economic effect on those small entities because the cost of requiring decommissioning cost summaries is not significant. (*See id.*)

This proposed rule could affect some additional companies (*i.e.,* ROW holders that were not covered by the December 2015 final rule as lessees or owners of operating rights) that would be required to submit pipeline decommissioning cost summaries. Using more recent information than was available to us when we published the December 2015 final rule, we estimate that the proposal to require reporting of pipeline decommissioning costs could affect approximately 111 lessees, owners of operating rights, and ROW holders that currently own or control DOI pipelines, including many companies already covered by the December 2015 final rule. Of these 111 potentially affected entities, we estimate that a substantial number (66 companies) are small entities. Therefore, this proposed rule would affect a substantial number of small entities.

However, the proposed rule would not impose significant economic impacts on the potentially affected small entities. The proposed requirement to submit pipeline decommissioning cost summaries would not result in significant additional costs or burdens for any affected entity. As indicated in the Paperwork Reduction Act section of this document, the annual burden of the proposed rule is estimated to be only 500 hours in total for all affected entities (whether or not small) to prepare and submit their pipeline decommissioning summaries. Accordingly, since the changes reflected in the proposed rule would not have a significant economic effect on a substantial number of small entities, the RFA does not require BSEE to prepare a regulatory flexibility analysis for this proposed rule.

Small Business Regulatory Enforcement Fairness Act (SBREFA)

This proposed rule is not a major rule under the SBREFA (5 U.S.C. 804(2)). This rule would not:

—Have an annual effect on the economy of $100 million or more;

—Cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or

—Have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

Your comments are important. The Small Business and Agriculture Regulatory Enforcement Ombudsman and 10 Regional Fairness Boards were established to receive comments from small businesses about Federal agency enforcement actions. The Ombudsman will annually evaluate the enforcement activities and rate each agency's responsiveness to small business. If you wish to comment on the actions of BSEE, call 1–888–734–3247. You may comment to the Small Business Administration (SBA) without fear of retaliation. Allegations of discrimination/retaliation filed with the SBA will be investigated for appropriate action.

Unfunded Mandates Reform Act of 1995

This proposed rule would not impose an unfunded mandate on State, Tribal, or local governments or the private sector of more than $100 million per year. The proposed rule also would not have a significant or unique effect on State, Tribal, or local governments or the private sector. Thus, a statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

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[4] BSEE recognizes that a designated operator may submit the required summary of decommissioning costs on behalf of a lessee.

Takings Implication Assessment (E.O. 12630)

Under the criteria in E.O. 12630, this proposed rule would not effect a taking or otherwise have takings implications. This proposed rule is not a governmental action capable of interference with constitutionally protected property rights. Therefore, a Takings Implication Assessment is not required.

Federalism (E.O. 13132)

Under the criteria in E.O. 13132, this proposed rule would not have federalism implications. This proposed rule would not have a substantial direct effect on the States or the relationship between the Federal and State governments. To the extent that State and local governments have a role in OCS activities, this proposed rule would not affect that role. Accordingly, a federalism summary impact statement is not required.

Civil Justice Reform (E.O. 12988)

This proposed rule complies with the requirements of E.O. 12988, *Civil Justice Reform* (February 7, 1996). Specifically, this rule:

—Meets the criteria of section 3(a) of E.O. 12988 requiring that all regulations be reviewed to eliminate drafting errors and ambiguity and be written to minimize litigation; and

—Meets the criteria of section 3(b)(2) of E.O. 12988 requiring that all regulations be written in clear language and contain clear legal standards.

Consultation With Indian Tribal Governments (E.O. 13175)

We have evaluated this proposed rule under the Department's tribal consultation policy and under the criteria in E.O. 13175 and have determined that it would have no substantial direct effects on federally recognized Indian tribes. As a result, consultation under the Department's tribal consultation policy is not required.

Paperwork Reduction Act (PRA)

This proposed rule contains an information collection (IC) that will be submitted to the OMB for review and approval under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). As part of our continuing effort to reduce paperwork and respondent burdens, BSEE invites the public and other Federal agencies to comment on any aspect of the reporting and recordkeeping burden. If you wish to comment on the IC aspects of this proposed rule, you may send your comments directly to OMB and send a copy of your comments to the Regulations and Standards Branch (for more information, see the **DATES** and **ADDRESSES** section of this document). Please refer to *Decommissioning Costs for Pipelines,* 1014–AA32, in your comments. BSEE specifically requests comments concerning the need for the information, its practical utility, the accuracy of the agency's burden estimate, and ways to minimize the burden. You may obtain a copy of the supporting statement for the new collection of information by contacting the Bureau's Information Collection Clearance Officer at (703) 787–1607. To see a copy of the entire IC request submitted to OMB, go to *http://www.reginfo.gov* (select Information Collection Review, Currently Under Review).

The title of the collection of information for this proposed rule is 30 CFR part 250, subpart Q, *Decommissioning Costs for Pipelines.* As with the other decommissioning expenditure information currently required to be submitted to BSEE under § 250.1704(i), summaries of actual pipeline decommissioning expenditures will help BSEE to better estimate future decommissioning costs for OCS pipelines. BOEM will then use BSEE's future pipeline decommissioning cost estimates to set necessary financial assurance levels to minimize or eliminate the possibility that the government will incur liability for future pipeline decommissioning.

Potential respondents comprise Federal OCS oil, gas, and sulfur lessees, owners of operating rights, and pipeline ROW holders. Responses to this collection are mandatory. The frequency of response is on occasion. The IC does not include questions of a sensitive nature. BSEE will protect confidential commercial and proprietary information according to FOIA (5 U.S.C. 552) and its implementing regulations (43 CFR part 2), and 30 CFR 250.197 (*Data and information to be made available to the public or for limited inspection*), and 30 CFR part 252 (*OCS Oil and Gas Information Program*).

Once the requirements of this proposed rulemaking have been codified, BSEE will consolidate these additional burden hours into the primary collection for 30 CFR part 250, subpart Q, under OMB Control Number 1014–0010 (expiration 10/31/16; 29,437 burden hours and $2,152,644 non-hour cost burdens). There are no non-hour cost burdens associated with this proposed rulemaking. The following table is a breakdown of the burden estimate:

BURDEN TABLE

Citation 30 CFR 250	Reporting and recordkeeping requirements	Hour burden	Average number of annual responses	Annual burden hours
250.1704(i)	Submit to the Regional Supervisor a complete summary of expenditures incurred within 120 days after completion of each decommissioning activity (including permanently plugging any well, removal of any platform or facility, decommissioning of pipelines, etc.).	1	500 pipeline summaries	500
250.1704(i)	Submit certified statement attesting to accuracy of the summary for expenditures incurred.	Exempt from the PRA under 5 CFR 1320.3(i)(1).		0
Total			500 responses	500

An agency may not conduct or sponsor and you are not required to respond to, a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act of 1969 (NEPA)

This proposed rule meets the criteria set forth in 516 Departmental Manual (DM) 15.4C(1) for a categorical exclusion because it involves modification of existing regulations, the impacts of which would be limited to administrative or economic effects with minimal environmental impacts.

We have also analyzed this proposed rule to determine if it meets any of the extraordinary circumstances set forth in 43 CFR 46.215 that would require an environmental assessment or an environmental impact statement for actions otherwise eligible for a categorical exclusion. We have concluded that this proposed rule would not meet any of the criteria for extraordinary circumstances.

Data Quality Act

In developing this proposed rule, we did not conduct or use a study, experiment, or survey requiring peer review under the Data Quality Act (44 U.S.C. 3516 *et seq.,*

Public Law 106–554, app. C § 515, 114 Stat. 2763, 2763A–153–154).

Effects on the Nation's Energy Supply (E.O. 13211)

This proposed rule would not be a significant energy action under E.O. 13211 because:

—It is not a significant regulatory action under E.O. 12866;

—It is not likely to have a significant adverse effect on the supply, distribution or use of energy; and

—It has not been designated as a significant energy action by the Administrator of OIRA.

Clarity of This Regulation (E.O. 12866 and E.O. 12988)

We are required by E.O. 12866 and E.O. 12988, and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

—Be logically organized;

—Use the active voice to address readers directly;

—Use clear language rather than jargon;

—Be divided into short sections and sentences; and

—Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in the **ADDRESSES** section. To better help us meet these requirements, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that you find unclear, which sections or sentences are too long, and the sections where you feel lists or tables would be useful.

List of Subjects in 30 CFR Part 250

Administrative practice and procedure, Continental Shelf, Environmental impact statements, Environmental protection, Government contracts, Investigations, Oil and gas exploration, Penalties, Reporting and recordkeeping requirements, Sulfur.

Janice M. Schneider,

Assistant Secretary, Land and Minerals Management.

For the reasons stated in the preamble, BSEE proposes to amend 30 CFR part 250 as follows:

PART 250—OIL AND GAS AND SULFUR OPERATIONS IN THE OUTER CONTINENTAL SHELF

■ 1. The authority citation for part 250 continues to read as follows:

Authority: 30 U.S.C. 1751, 31 U.S.C. 9701, 33 U.S.C. 1321(j)(1)(C), 43 U.S.C. 1334.

■ 2. Amend § 250.1704 by revising paragraphs (i) and (j) in the table to read as follows:

§ 250.1704 What decommissioning applications and reports must I submit and when must I submit them?

* * * * *

Decommissioning applications and reports	When to submit	Instructions
* * *	*	* * *
(i) A certified summary of expenditures for permanently plugging any well, removal of any platform or other facility, clearance of any site after wells have been plugged or platforms or facilities removed, and decommissioning of pipelines.	Within 120 days after completion of each decommissioning activity specified in this paragraph.	Submit to the Regional Supervisor a complete summary of expenditures actually incurred for each decommissioning activity (including, but not limited to, the use of rigs, vessels, equipment, supplies and materials; transportation of any kind; personnel; and services). Include in, or attach to, the summary a certified statement by an authorized representative of your company attesting to the truth, accuracy and completeness of the summary. The Regional Supervisor may provide specific instructions or guidance regarding how to submit the certified summary.
(j) If requested by the Regional Supervisor, additional information in support of any decommissioning activity expenditures included in a summary submitted under paragraph (i) of this section.	Within a reasonable time as determined by the Regional Supervisor.	The Regional Supervisor will review the summary and may provide specific instructions or guidance regarding the submission of additional information (including, but not limited to, copies of contracts and invoices), if requested, to complete or otherwise support the summary.

[FR Doc. 2016–19057 Filed 8–11–16; 8:45 am]

BILLING CODE 4310–VH–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 4

RIN 2900–AP27

Schedule for Rating Disabilities; Skin Conditions

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) proposes to amend the portion of the VA Schedule for Rating Disabilities (VASRD or Rating Schedule) that addresses skin conditions. The purpose of these changes is to incorporate medical advances that have occurred since the last review, update current medical terminology, and provide clear evaluation criteria. The proposed rule reflects advances in medical knowledge, recommendations from the Skin Disorders Work Group, which is comprised of subject matter experts from both the Veterans Benefits Administration and the Veterans Health Administration, and comments from experts and the public gathered as part of a public forum. The public forum, focusing on revisions to the skin conditions section of the VASRD, was held in January 2012.

DATES: *Comment Date:* Comments must be received by VA on or before October 11, 2016.

Applicability Date: The provisions of this rulemaking shall apply to all applications for benefits that are received by VA or that are pending before the agency of original jurisdiction on or after the effective date of the final rule. The Secretary does not intend for the provisions of this rulemaking to apply to claims that have been certified for appeal to the Board of Veterans' Appeals or are pending before the Board of Veterans' Appeals, the United States Court of Appeals for Veterans Claims, or the United States Court of Appeals for the Federal Circuit.

ADDRESSES: Written comments may be submitted through *www.Regulations.gov;* by mail or hand-delivery to Director, Regulation Policy and Management (02REG), Department of Veterans Affairs, 810 Vermont Avenue NW., Room 1068, Washington, DC 20420; or by fax to (202) 273–9026. (This is not a toll free number.) Comments should indicate that they are submitted in response to "RIN 2900–AP27-Schedule for Rating Disabilities; Skin Conditions." Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1068, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461–4902 for an appointment. (This is not a toll free number.) In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at *www.Regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Gary Reynolds, M.D., Regulations Staff (211C), Compensation Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 461–9700. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: The National Defense Authorization Act For Fiscal Year 2004, sec. 1501–07, Public Law 108–136, 117 Stat. 1392, established the Veterans' Disability Benefits Commission (Commission). Section 1502 of Public Law 108–136 mandated the Commission to study ways to improve the disability compensation system for disabled military veterans. The Commission consulted with the Institute of Medicine (IOM) to review the medical aspects of the current disability compensation policies for veterans. In 2007, the IOM released its report titled, "A 21st Century System for Evaluating Veterans for Disability Benefits."

The IOM Report was notable in several respects. The IOM observed, in part, that the VASRD was inadequate at times because it contained obsolete information and did not sufficiently integrate current and accepted diagnostic procedures. In addition, the IOM observed that the current body system organization of the VASRD does not reflect current knowledge of the relationships between conditions and comorbidities. Institute of Medicine, Committee on Medical Evaluation of Veterans for Disability Compensation, "A 21st Century System for Evaluating Veterans for Disability Benefits," 113 (Michael McGeary et al. eds. 2007).

Following release of the IOM report, VA created a Skin Disorders Work Group (Work Group). The goals adopted by the Work Group were to: 1) improve and update the criteria that VA uses to assign levels of disability after service connection is granted; 2) improve the level of fairness in adjudication of benefits related to service connected disabilities of Veterans; and 3) invite public participation. The Work Group was led by co-chairs from the Veterans Health Administration (VHA) and Veterans Benefits Administration (VBA). The workgroup was comprised of subject matter experts (SMEs) from within VA, DoD, and medical academia. In addition, members from several Veterans Service Organizations (VSOs) were invited to participate as representatives from the public. The Work Group held a public forum in New York City during January 2012, where several SMEs gave presentations focused on their particular area(s) of expertise.

After the public forum, the Work Group met periodically to continue the revision efforts. Participants from VBA, VHA, medical academia, and VSO representatives continued work within their areas of expertise. The regulation drafting phase began in September 2013, and continues through the publication of this proposed rule. The rule VA proposes is consistent with updating and improving criteria by using validated severity ratings specific to the skin for each of the disability rating levels. As discussed in more detail below, the newly adopted classifications are derived from current medical practice.

Schedule of Ratings—Skin Conditions

General Rating Formula for Skin Disorders

Section 4.118 currently lists 30 diagnostic codes (DCs) encompassing conditions involving injury or disease of the skin. VA proposes to revise these codes, through addition, removal, or other revisions, to reflect current medical science, terminology, and functional impairment.

VA would delete the current introductory paragraph to § 4.118. VA added the current paragraph to explain the applicability of the 2008 amendments to § 4.118, DCs 7800, 7801, 7802, 7804, and 7805. This rulemaking would make further amendments and would render outdated the current introductory paragraph. VA would add an applicability date paragraph to the dates section to explain this rulemaking's applicability. The existing provisions in § 4.118 concerning review of ratings and effective dates merely reflect generally applicable principles that need not be restated in the rating schedule.

VA would add a new introductory paragraph to state that, for the purposes of § 4.118, systemic therapy is treatment that is administered through any route (orally, injection, suppository, intranasally) other than the skin, and topical therapy is treatment that is administered through the skin. On March 1, 2016, the United States Court of Appeals for Veterans Claims (Veterans Court) found it "unambiguous" that the "use of a topical corticosteroid is systemic therapy within the meaning of Diagnostic Code 7806." *Johnson* v. *McDonald,* 27 Vet. App. 497, 502, 504 (2016). Under this holding, repeated localized application of topical corticosteroid could entitle a veteran to a disability rating as high as sixty percent, even if the affected area is very small. *Johnson* creates a dramatic disconnect between the severity of the veteran's disability and the corresponding rating. Therefore, VA is amending § 4.118 to clearly provide that VA does not intend for treatment administered through the skin (topical therapy) to constitute systemic therapy. VA notes that it is possible for topical treatments to have systemic effects if administered on a large enough scale. However, in these situations, a veteran can obtain a higher rating due to the percentage of the body affected, not the mode of administration for his or her treatment. For example, if more than 40 percent of a veteran's body is covered in eczema and a veteran treats all affected areas with topical corticosteroid, the veteran will be entitled to a 60 percent rating due to the percentage of the body affected, not because he is taking systemic therapy.

VA proposes a General Rating Formula to evaluate several of the skin disorders: dermatitis or eczema (DC 7806), discoid lupus erythematosus (DC 7809), dermatophytosis (DC 7813), bullous disorders (DC 7815), psoriasis (DC 7816), infections of the skin not listed elsewhere (DC 7820), cutaneous manifestations of collagen-vascular diseases not listed elsewhere (DC 7821), papulosquamous disorders not listed elsewhere (DC 7822), and diseases of keratinization (DC 7824). Individually, each of the above referenced conditions involves similar superficial components of the skin. The severity of impairment for each condition increases as more skin is involved. All of the conditions have treatments which are applied directly to the skin, as well as taken systemically (*e.g.,* by mouth). There are still more similarities with regard to which treatments are used, treatment dosages given, treatment routes of administration, and treatment duration. As a result, VA concluded it would be more efficient to rate under the same formula, rather than to prescribe individual rating criteria.

Similar to how these DCs are currently evaluated, this General Rating Formula accounts for percentages of areas affected, both of the entire body and exposed areas, as well as the level of treatment required. The percentage evaluations assigned under the General Rating Formula mirror the percentage evaluations currently assigned for these DCs. Specifically, VA proposes a 60 percent evaluation when at least one of the following is present: More than 40 percent of the entire body or more than 40 percent of exposed areas affected, or; Constant or near-constant systemic therapy including, but not limited to, corticosteroids, phototherapy, retinoids, biologics, photochemotherapy, PUVA or other immunosuppressive drugs required per 12-month period. VA proposes a 30 percent evaluation when at least one of the following is present: 20 to 40 percent of the entire body or 20 to 40 percent of exposed areas affected, or; Systemic therapy including, but not limited to, corticosteroids, phototherapy, retinoids, biologics, photochemotherapy, PUVA or other immunosuppressive drugs required for a total duration of six weeks or more, but not constantly, per 12-month period. VA proposes a 10 percent evaluation when at least one of the following is present: At least 5 percent, but less than 20 percent of the entire body affected, or; At least 5 percent, but less than 20 percent of exposed areas affected, or; Intermittent systemic therapy including, but not limited to, corticosteroids, phototherapy, retinoids, biologics, photochemotherapy, PUVA or other immunosuppressive drugs required for a total duration of less than six weeks per 12-month period. VA proposes a zero percent evaluation when no more than topical therapy is required per 12-month period and at least one of the following is present: Less than 5 percent of the entire body affected, or; Less than 5 percent of exposed areas affected.

Additionally, VA proposes to maintain the current rating instruction for DCs 7806, 7809, 7813–7816, and 7820–7822 which allows for evaluation under disfigurement of the head, face, or neck (DC 7800) or scars (DCs 7801, 7802, 7804, or 7805), depending upon the predominant disability, in lieu of using the General Rating Formula. This rating instruction does not apply to current or new DC 7824, and therefore, VA proposes to add a clarifying sentence to that effect to this instruction.

As for the expanded list of systemic therapies identified in the General Rating Formula, VA notes that the current VASRD lists only "corticosteroids or other immunosuppressive drugs" as examples of systemic therapy. However, since the last review and update of the schedule of disability ratings for the skin, a number of new systemic therapies have surfaced that are used to treat the conditions covered under the General Rating Formula. These include phototherapy, retinoids, biologics, photochemotherapy, and PUVA (*e.g.,* ultraviolet therapy). See, *e.g.,* Jennifer D. Peterson, MD, et al., "A Comprehensive Management Guide for Atopic Dermatitis," 18:6 Dermatology Nursing, 531–42 (2006); "Psoriasis Medications," WebMD, *http://www.webmd.com/skin-problems-and-treatments/psoriasis/psoriasis-medications* (last visited Aug. 25, 2015). To ensure consistent evaluation of these conditions, VA proposes to add these systemic therapies to the list of enumerated treatments.

In addition to creating the General Rating Formula and applying it to DCs 7806, 7809, 7813, 7815, 7816, 7820, 7821, 7822, and 7824, VA proposes to amend certain individual DCs within § 4.118. The particular changes affecting each DC immediately follow.

Diagnostic Codes 7801 and 7802

Each of these DCs pertains to types of scars which are, in part, characterized as "nonlinear." To broaden application of these DCs, VA proposes to remove the reference to "nonlinear" from each DC title. In addition, VA proposes to include a more descriptive reference to whether the scar involves underlying soft tissue damage in place of the current terms "superficial" and "deep"—to assist rating personnel. This latter proposed change eliminates the need for current note (1) in each DC, as well as the last sentence in note (2) in each DC; therefore, VA proposes removal of those items.

Currently, if a scar runs in two or more separate areas of the body, note (2) for DCs 7801 and 7802 is intended to allow for the assignment of a separate evaluation for each affected zone and then to combine those evaluations under 38 CFR 4.25. See 73 FR 54708, 54709, Sept. 23, 2008. Although VA has been applying note (2) in this way, VA finds that the note could be written more clearly. Therefore, VA proposes to rewrite note (2) in a clearer and more concise manner and to add a new note (1) to be placed under both DCs 7801 and 7802 that would define the zones of the body. Specifically, note (1) would define the six zones of the body as each extremity, the anterior trunk, and the posterior trunk. VA also proposes to move the statement that the midaxillary line is what divides the anterior and posterior trunk from note (2) to note (1).

Additionally, VA proposes to add language to note (2) to allow for an alternative evaluation. Specifically, VA proposes to allow for a single evaluation under DCs 7801 and 7802 if adding the entire affected zones of the body together would result in a higher evaluation. VA proposes this additional evaluation method in order to accurately reflect the level of disability present. In some circumstances, combining the scars from different zones under § 4.25 results in a lower compensation level than if the total scar area was added together without regard to the zone involved. For example, under DC 7801, if there is a single scar of 6 square inches total equally affecting both the anterior and posterior trunk, a compensable rating would not be warranted because the area affecting each zone would be less than 6 square inches total (*e.g.,* 3 square inches on the anterior trunk and 3 square inches on the posterior trunk). However, when adding these scar segments together to consider the total square area (6 square inches), a 10 percent evaluation would be warranted. Similarly, under DC 7802, there may be scars in separate zones that are not each 144 square inches, but which add up to 144 square inches total. For example, a veteran may have a 100 square inch scar on the anterior trunk and a 100 square inch scar on the posterior trunk, which would not warrant a compensable rating under DC 7802. However, an evaluation of 10 percent would be warranted by adding the affected zones together for both scars, as they total to 200 square inches together.

Diagnostic Code 7803

This DC was deleted in October 2008. See 73 FR at 54710. However, several criteria reference this code. VA proposes to delete any and all references to DC 7803.

Diagnostic Code 7805

VA proposes to remove the reference to "linear" scars from DC 7805. The result of this change is that this DC applies to both linear and non-linear scars. As discussed above, VA proposes to remove the reference to "nonlinear" scars from DCs 7801 and 7802, expanding application of these codes to linear scars. Thus, the reference to linear scars should be removed from DC 7805 to avoid confusion by rating personnel.

Diagnostic Codes 7809 and 7821

VA proposes to retitle both DC 7809 and DC 7821 using current medical terminology. Current DC 7809 refers to "Discoid lupus erythematosus or subacute cutaneous lupus erythematosus." VA proposes to remove the listed condition "subacute cutaneous lupus erythematosus" from DC 7809 and add it to DC 7821. The proposed DC 7809 will read as "Discoid lupus erythematosus. Current DC 7809 also provides that a rating under DC 7809 should not be combined with a rating under DC 6350. In order to maintain this provision, we would add a note to DC 7809. The rationale for transferring subacute cutaneous lupus erythematosus from DC 7809 to DC 7821 is that subacute cutaneous lupus erythematosus is a distinctly different condition which is more analogous to collagen-vascular diseases not listed elsewhere (*e.g.,* DC 7821) than it is to discoid lupus erythematosus. See Jean L. Bolognia, John L. Jorrizo, et al. eds., "Dermatology," 618–20 (3d ed. 2012). The proposed DC 7821 will read as "Cutaneous manifestations of collagen-vascular diseases not listed elsewhere (including scleroderma, calcinosis cutis, subacute cutaneous lupus erythematosus, and dermatomyositis)." There is no change in the evaluation criteria; both conditions would be rated under the General Rating Formula.

Diagnostic Code 7813

Current DC 7813 describes a number of variations of dermatophytosis, including tinea corporis, tinea capitis, tinea pedis, tinea barbae, tinea unguium, and tinea cruris. To update this DC title with current medical terminology, VA proposes to add "tinea versicolor" to this list as well as a parenthetical for tinea unguium—onychomycosis as these are also common variations of dermatophytosis seen in the veteran population. Id. at 1251–84. As previously discussed above, VA intends to rate conditions covered by DC 7813 under the General Rating Formula, which provides for similar evaluation criteria as are currently in effect.

Diagnostic Codes 7815 and 7816

Current medical practice indicates conditions rated under DC 7815 (bullous disorders) and DC 7816 (psoriasis) can affect additional areas beyond the skin (bullous disorders can affect mucosa of the ocular, oral, gastrointestinal, respiratory, and genitourinary tracts; psoriasis can affect oral mucosa, nails and the joints). Id. at 142, 148–55, 472–73, 482, and 487–89. Therefore, in addition to rating these conditions under the General Rating Formula, VA proposes a note for each of these DCs. The note to DC 7815 would instruct the rater to rate complications and residuals of mucosal involvement (ocular, oral, gastrointestinal, respiratory, and genitourinary) separately under the appropriate diagnostic code. The note to DC 7816 would instruct the rater to rate complications such as psoriatic arthritis and other clinical manifestations (oral mucosa, nails) under the appropriate diagnostic code.

Diagnostic Code 7817

VA proposes to retitle DC 7817, currently "Exfoliative dermatitis (erythroderma)," as "Erythroderma." Erythroderma is the nomenclature being used in current medical practice. Id. at 171–81. In addition, it proposes to update the rating criteria to reflect up-to-date medical understanding of this condition. VA would also slightly reorganize the presentation of criteria for ease of field use. Currently, this condition is evaluated based upon level of involvement of the skin, presence of systemic manifestations, and the level of treatment required. VA does not propose any changes to the level of involvement of the skin, presence of systemic manifestations, or the level of treatment required. However, similar to the changes proposed in the General Rating Formula, the new rating criteria for DC 7817 would reflect additional systemic treatments appropriate for this condition. Currently, DC 7817 includes corticosteroids, immunosuppressive retinoids, PUVA (psoralen with long-wave ultraviolet-A light) or UVB (ultraviolet-B light) treatments, or electron beam therapy. VA proposes to add biologics to this list as several biological therapies have been approved for treatment of skin disorders in recent years. See M. Viguier, et al., "Efficacy and Safety of Biologics in Erythrodermic Psoriasis," The British J. of Dermatology 167(2): 417–23 (2012). VA proposes that inclusion of this type of systemic therapy in the rating criteria would ensure consistent and accurate evaluations.

In addition to expanding the list of systemic therapies listed, VA proposes to include a criterion which considers an individual's level of response to treatment for both the 60 percent and 100 percent evaluations. Under the new criteria, VA would provide a 100 percent rating when the veteran is not currently undergoing treatment due to a documented history of treatment failure with 2 or more treatment regimens and a 60 percent rating when the veteran is not currently undergoing treatment due to a documented history of treatment failure with 1 treatment regimen. Historically, there have been a significant number of veterans with this disorder who fail to respond to treatment (frequently, the condition is related to an underlying malignancy that is not treated successfully, hence the treatment failure).

To assist rating personnel in applying the new rating criteria, VA proposes to add a note to DC 7817 which defines "treatment failure." Modeled after a formula developed to study the efficacy of treatment in erythrodermic cutaneous T-cell lymphoma, VA proposes to define "treatment failure" as either disease progression or less than a 25 percent reduction in the extent and severity of disease after four weeks of prescribed therapy, as documented by medical records. See Zackheim HS, Kashani-Sabet M, et al., "Low-dose methotrexate to treat erythrodermic cutaneous T-cell lymphoma: Results in twenty-nine patients," J. Am. Acad. of Dermatology 34(4):626–31 (1996); see also Bolognia, supra at 181 (erythroderma usually improves within two to six weeks of initiation).

Diagnostic Code 7822

VA proposes to update the description in this code to reflect current medical practice. Specifically, the condition mycosis fungoides is added to the list of papulosquamous disorders. See Bolognia, 2019–2027. Currently, mycosis fungoides is not listed in the rating schedule and has caused confusion among VA rating specialists on how to account for this condition, leaving VA rating specialists to invoke § 4.20, analogous ratings. This approach could lead to inconsistent ratings for this condition. Therefore, adding mycosis fungoides under DC 7822 would eliminate the need for an analogous rating and provide a consistent basis for evaluating this condition.

Diagnostic Code 7825

Chronic urticaria, also known as chronic hives, is defined as continuous urticaria at least twice per week off treatment for a period of six weeks or more. See Bolognia at 295. It can be caused by a number of mechanisms (physical stimulus, or touch; autoimmune causes; pseudoallergenic, infection-related; vasculitis-related; and, idiopathic, or unknown). Id. at 296. Chronic urticaria is currently evaluated based on the frequency of "episodes" or "debilitating episodes" and type of treatment. Regarding "episodes" or "debilitating episodes," VA believes this term is non-specific and not helpful to rating personnel in evaluating this condition. Therefore, VA proposes to replace this term with "documented urticarial attacks." Furthermore, VA proposes to revise all of the rating criteria to indicate both a minimum specified frequency of documented urticarial attacks within a 12 month period and the type of treatment required. VA proposes this approach to the criteria to introduce greater objectivity within the evaluation criteria based on current medical practice. VA acknowledges that an urticarial attack generally results in debilitation; however, this change makes it clear that the acute period of debilitation must be related to the service-connected skin disease itself rather than another condition.

Regarding the current 30 percent and 60 percent criteria, VA proposes to include examples of common "immunosuppressive therapy," to include, but not limited to, cyclosporine or steroids. See Bolognia, supra at 300–05. For clarity and consistency, VA would replace the phrase occurring "at least four times during the past 12-month period" in the 30 and 60 percent criteria with "four or more times per 12-month period."

VA also proposes to add two new sets of criteria under the 10 percent evaluation; the revised criteria would allow a 10 percent evaluation to be assigned in more circumstances based upon an individual's level of response to treatment. A 10 percent evaluation would be assigned if there are recurrent documented urticarial attacks occurring one to three times during the past 12-month period and intermittent systemic immunosuppressive therapy is required for control. VA would also assign a 10 percent evaluation if there are recurrent documented urticarial attacks occurring four or more times during the past 12-month period and treatment with antihistamines or sympathomimetics (including, but not limited to an epipen or intramuscular epinephrine) is required or, if there are no recurrent documented urticarial attacks, but continuous systemic immunosuppressive therapy medication is required for control (including, but not limited to, cyclosporine, steroids). VA also proposes to reorganize how the various criteria are presented for ease of field use.

VA believes that a 10 percent evaluation is appropriate in each of these cases because the treatment measures may impose slight disability upon the individual. For example, long term treatment with antihistamines can result in drowsiness (even the non-sedating kinds) and autonomic nervous system dysfunction (*e.g.,* urinary retention). Id. at 303. Similarly, continuous use of systemic medications may result in disabling effects, such as drowsiness with doxepin or weight gain, and increased risk of diabetes with long-term steroid use. See Manuchair Ebadi, "Desk Reference of Clinical Pharmacology," 101, 113, 329, and 582 (2d ed. 2008); see also "Chronic hives (urticaria)," Mayo Clinic (Sept. 17, 2011), *http://www.mayoclinic.org/diseases-conditions/chronic-hives/basics/treatment/con-20031634* (last visited Apr. 23, 2014).

Diagnostic Code 7826

Similar to DC 7825, VA proposes to update the criteria under current DC 7826, "Vasculitis, primary cutaneous." First, VA proposes to replace the term "debilitating episodes," which is a non-specific term not defined in the VASRD with the term "documented vasculitic episodes." This change in terminology is more consistent with current medical practice. Next, VA proposes to modify the criteria to specify the minimum frequency of documented vasculitic episodes, the type of treatment required and the effectiveness of that treatment. In turn, increased disability would be reflected in objective terms (*e.g.,* increased frequency of vasculitic episodes, more intensive treatment or lack of treatment effectiveness). VA also proposes to reorganize how the various criteria are presented for ease of field use. These modifications incorporate current medical knowledge, enhance objectivity and are easier for rating personnel to utilize.

For the 60 percent level of compensation, VA proposes to remove the phrase "occurring at least four times during the past 12 month period" and replace the term "recurrent" with "persistent" and the term "despite" with the phrase "refractory to." The phrase removal and term replacements are to more clearly differentiate between the 60 percent and 30 percent compensation levels. For the 30 percent evaluation, VA proposes to replace the phrase ". . . at least four times during the past 12-month period . . ." with the phrase "four or more times per 12-month period" to clearly delineate the minimal frequency requirement and ease of field use. For the 10 percent evaluation, VA proposes to replace the phrase "one to three times during the past 12-month period" with "one to three times per 12-month period" for ease of field use. Additionally for the 10 percent evaluation, VA proposes to add that the absence of recurrent documented vasculitic episodes but requiring continuous systemic medication for control would also warrant compensation. This proposed revision allows a 10 percent evaluation to be assigned in more circumstances, namely, when the disorder is controlled through the use of systemic medications, but there may be slight disabling effects as a result of such medication. See Ebadi, supra; see also

"Vasculitis," Mayo Clinic (Oct. 8, 2011), *http://www.mayoclinic.org/diseases-conditions/vasculitis/basics/treatment/con-20026049* (last visited Apr. 23, 2014).

Diagnostic Code 7827

VA proposes to revise and update the criteria for DC 7827, "Erythema multiforme; Toxic epidermal necrolysis." First, each evaluation level would reference the presence of mucosal (leading to impaired mastication, that is, chewing), palmar (leading to impaired handgrip), or plantar involvement (leading to impaired ambulation, that is, walking). See Bolognia, supra at 320, 322, and 326–32. The mucosal, palmar, and/or plantar findings would be restricted to the past 12-month period for all evaluation levels. For clarity and consistency, VA would replace the phrase occurring "at least four times during the past 12-month period" in the 30 and 60 percent criteria with "four or more times per 12-month period." For a 60 percent evaluation, recurrent mucosal, palmar, or plantar involvement impairing mastication, use of hands, or ambulation occurring four or more times per 12-month period despite ongoing immunosuppresive therapy would be required. For a 30 percent evaluation, recurrent mucosal, palmar, or plantar involvement not impairing mastication, use of hands, or ambulation occurring four or more times per 12-month period, and requiring intermittent systemic therapy would be required.

A 10 percent evaluation would be assigned for the following circumstances: (1) One to three episodes of mucosal, palmar, or plantar involvement not impairing mastication, use of hands, or ambulation occurring per 12-month period AND requiring intermittent systemic therapy, or (2) without recurrent episodes, but requiring continuous systemic medication for control. This allows a 10 percent evaluation to be assigned in more circumstances, based upon the level of response to treatment. Lastly, VA proposes to add a note at the end of DC 7827 defining, for the purposes of DC 7827 only, that systemic therapy may consist of one or more of the following treatment agents: Immunosuppressives, antihistamines, or sympathomimetics. See Ebadi, supra; see also Victor Cohen, PharmD, et al., "Toxic Epidermal Necrolysis Treatment & Management," MEDSCAPE REFERENCE (Mar. 3, 2014), *http://emedicine.medscape.com/article/229698-treatment#a1156* (last visited Apr. 23, 2014).

Diagnostic Code 7828

VA proposes to update DC 7828, "Acne," by removing the reference to "superficial cysts" in the zero percent rating criteria. This update is proposed based upon current medical terminology as the term "superficial cysts" is no longer used in the medical community. See Bolognia, supra at 547–50 and 555–58.

Diagnostic Code 7829

Current DC 7829 instructs rating personnel to evaluate chloracne based, in part, on either the presence of deep or superficial acne. The current evaluation criteria instructs that either a 10 or 30 percent evaluation should be assigned depending upon whether more or less than 40 percent of the face and neck are involved; VA does not propose changes to these criteria. However, a 10 percent evaluation is also assigned when there is "deep acne other than on the face and neck." VA proposes to clarify that a 10 percent evaluation should only be assigned when deep acne affects non-intertriginous areas of the body other than the face and neck or less than 40 percent of the face and neck. Intertriginous areas of the body include the axilla of the arm, the anogenital region, and skin folds of the breast or between digits. Samuel T. Selden, MD, "Intertrigo,"Medscape Reference (Mar. 27, 2012), *http://emedicine.medscape.com/article/1087691-overview* (last visited Apr. 23, 2014). Deep acne affecting these areas of the body results in greater functional impairment to the individual because these represent more sensitive areas of the body. Therefore, VA proposes to assign a higher 20 percent evaluation when deep acne affects the intertriginous areas of the body.

Additionally, for reasons previously discussed in DC 7828, VA proposes to remove the term "superficial cysts" from the rating criteria under the zero percent evaluation. See Bolognia, supra at 547–50 and 555–58.

Technical Amendments

VA also proposes several technical amendments. We would update Appendix A, B, and C of part 4 to reflect the above noted proposed amendments.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a "significant regulatory action," requiring review by the Office of Management and Budget (OMB), unless OMB waives such review, as "any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order."

The economic, interagency, budgetary, legal, and policy implications of this regulatory action have been examined, and it has been determined not to be a significant regulatory action under Executive Order 12866. VA's impact analysis can be found as a supporting document at *http://www.regulations.gov,* usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA's Web site at *http://www.va.gov/orpm/,* by following the link for "VA Regulations Published From FY 2004 Through Fiscal Year to Date."

Regulatory Flexibility Act

The Secretary hereby certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (5 U.S.C. 601–612). This proposed rule would directly affect only individuals and would not directly affect small entities. Therefore, pursuant to 5 U.S.C. 605(b), this rulemaking is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. This proposed rule would have no such effect on State, local, and tribal governments, or on the private sector.

Paperwork Reduction Act

This proposed rule contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521).

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are 64.104, Pension for Non-Service-Connected Disability for Veterans; 64.109, Veterans Compensation for Service-Connected Disability; and 64.110, Veterans Dependency and Indemnity Compensation for Service-Connected Death.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Gina S. Farrisee, Deputy Chief of Staff, Department of Veterans Affairs, approved this document on August 1, 2016, for publication.

List of Subjects in 38 CFR Part 4

Disability benefits, Pensions, Veterans.

Dated: August 1, 2016.

Jeffrey Martin,

Office Program Manager, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

For the reasons set out in the preamble, the Department of Veterans Affairs proposes to amend 38 CFR part 4, subpart B as follows:

PART 4—SCHEDULE FOR RATING DISABILITIES

Subpart B—Disability Ratings

■ 1. The authority citation for part 4 continues to read as follows:

Authority: 38 U.S.C. 1155, unless otherwise noted.

■ 2. Amend § 4.118 by:

■ a. Revising the introductory paragraph;

■ b. Revising the entries for diagnostic codes 7801, 7802, and 7805;

■ c. Adding an entry for "General Rating Formula For The Skin For DCs 7806, 7809, 7813–7816, 7820–7822, And 7824", to appear after the entry for diagnostic code 7805;

■ d. Revising entries for diagnostic codes 7806, 7809, 7813, 7815, 7816, 7817, 7820, 7821, 7822, 7824, 7825, 7826, 7827, 7828, and 7829.

The revisions and additions read as follows:

§ 4.118 Schedule of ratings–skin.

For the purposes of this section, systemic therapy is treatment that is administered through any route (orally, injection, suppository, intranasally) other than the skin. For the purposes of this section, topical therapy is treatment that is administered through the skin.

	Rating
* * * * * * *	
7801 Burn scar(s) or scar(s) due to other causes, not of the head, face, or neck, that are associated with underlying soft tissue damage:	
Area or areas of 144 square inches (929 sq. cm.) or greater	40
Area or areas of at least 72 square inches (465 sq. cm.) but less than 144 square inches (929 sq. cm.)	30
Area or areas of at least 12 square inches (77 sq. cm.) but less than 72 square inches (465 sq. cm.)	20
Area or areas of at least 6 square inches (39 sq. cm.) but less than 12 square inches (77 sq. cm.)	10
Note (1): For the purposes of DCs 7801 and 7802, the six (6) zones of the body are defined as each extremity, anterior trunk and posterior trunk. The midaxillary line divides the anterior trunk from the posterior trunk	
Note (2): A separate evaluation may be assigned for each affected zone of the body under this diagnostic code if there are multiple scars, or a single scar, affecting multiple zones of the body. Combine the separate evaluations under § 4.25. Alternatively, if a higher evaluation would result from adding the areas affected from multiple zones of the body, a single evaluation may also be assigned under this diagnostic code.	
7802 Burn scar(s) or scar(s) due to other causes, not of the head, face, or neck, that are not associated with underlying soft tissue damage:	
Area or areas of 144 square inches (929 sq. cm.) or greater	10
Note (1): For the purposes of DCs 7801 and 7802, the six (6) zones of the body are defined as each extremity, anterior trunk and posterior trunk. The midaxillary line divides the anterior trunk from the posterior trunk.	
Note (2): A separate evaluation may be assigned for each affected zone of the body under this diagnostic code if there are multiple scars, or a single scar, affecting multiple zones of the body. Combine the separate evaluations under § 4.25. Alternatively, if a higher evaluation would result from adding the areas affected from multiple zones of the body, a single evaluation may also be assigned under this diagnostic code.	
* * * * * * *	
7805 Scars, other; and other effects of scars evaluated under diagnostic codes 7800, 7801, 7802, and 7804:	
Evaluate any disabling effect(s) not considered in a rating provided under diagnostic codes 7800–04 under an appropriate diagnostic code.	
General Rating Formula For The Skin For DCs 7806, 7809, 7813–7816, 7820–7822, And 7824:	
At least one of the following	
More than 40 percent of the entire body or more than 40 percent of exposed areas affected, or;	60
Constant or near-constant systemic therapy including, but not limited to, corticosteroids, phototherapy, retinoids, biologics, photochemotherapy, PUVA or other immunosuppressive drugs required per 12-month period.	
At least one of the following	30
20 to 40 percent of the entire body or 20 to 40 percent of exposed areas affected, or;	

	Rating
Systemic therapy including, but not limited to, corticosteroids, phototherapy, retinoids, biologics, photochemotherapy, PUVA or other immunosuppressive drugs required for a total duration of six weeks or more, but not constantly, per 12-month period.	
At least one of the following	10
At least 5 percent, but less than 20 percent of the entire body affected, or;	
At least 5 percent, but less than 20 percent of exposed areas affected, or;	
Intermittent systemic therapy including, but not limited to, corticosteroids, phototherapy, retinoids, biologics, photochemotherapy, PUVA or other immunosuppressive drugs required for a total duration of less than six weeks per 12-month period.	
No more than topical therapy required per 12-month period and at least one of the following	0
Less than 5 percent of the entire body affected, or;	
Less than 5 percent of exposed areas affected.	
Or rate as disfigurement of the head, face or neck (DC 7800) or scars (DCs 7801, 7802, 7804, or 7805), depending upon the predominant disability. This rating instruction does not apply to DC 7824.	
7806 Dermatitis or eczema.	
Evaluate under the General Rating Formula for the Skin.	
* * * * * * *	
7809 Discoid lupus erythematosus.	
Evaluate under the General Rating Formula for the Skin.	
Note: Do not combine with ratings under DC 6350.	
* * * * * * *	
7813 Dermatophytosis (ringworm: of body, tinea corporis; of head, tinea capitis; of feet, tinea pedis; of beard area, tinea barbae; of nails, tinea unguium (onychomycosis); of inguinal area (jock itch), tinea cruris; tinea versicolor)	
Evaluate under the General Rating Formula for the Skin.	
7815 Bullous disorders (including pemphigus vulgaris, pemphigus foliaceous, bullous pemphigoid, dermatitis herpetiformis, epidermolysis bullosa acquisita, benign chronic familial pemphigus (Hailey-Hailey), and porphyria cutanea tarda).	
Evaluate under the General Rating Formula for the Skin.	
Note: Rate complications and residuals of mucosal involvement (ocular, oral, gastrointestinal, respiratory, and genitourinary) separately under the appropriate diagnostic code.	
7816 Psoriasis.	
Evaluate under the General Rating Formula for the Skin.	
Note: Rate complications such as psoriatic arthritis and other clinical manifestations (oral mucosa, nails) under the appropriate diagnostic code.	
7817 Erythroderma:	
Generalized involvement of the skin with systemic manifestations (such as fever, weight loss, and hypoproteinemia) AND one of the following:	
Constant or near-constant systemic therapy such as therapeutic doses of corticosteroids, immunosuppressive retinoids, PUVA (psoralen with long-wave ultraviolet-A light); UVB (ultraviolet-B light) treatments, biologics, or electron beam therapy required per 12-month period, or	
No current treatment due to a documented history of treatment failure with 2 or more treatment regimens	100
Generalized involvement of the skin without systemic manifestations and one of the following:.	
Constant or near-constant systemic therapy such as therapeutic doses of corticosteroids, immunosuppressive retinoids, PUVA (psoralen with long-wave ultraviolet-A light); UVB (ultraviolet-B light) treatments, biologics, or electron beam therapy required per 12-month period, or	
No current treatment due to a documented history of treatment failure with 1 treatment regimen	60
Any extent of involvement of the skin, and any of the following therapies required for a total duration of six weeks or more, but not constantly, per 12-month period: Systemic therapy such as therapeutic doses of corticosteroids, immunosuppressive retinoids, PUVA (psoralen with long-wave ultraviolet-A light) or UVB (ultraviolet-B light) treatments, biologics, or electron beam therapy	30
Any extent of involvement of the skin, and any of the following therapies required for a total duration of less than six weeks per 12-month period: Systemic therapy such as therapeutic doses of corticosteroids, immunosuppressive retinoids, PUVA (psoralen with long-wave ultraviolet-A light) or UVB (ultraviolet-B light) treatments, biologics, or electron beam therapy	10
Any extent of involvement of the skin, and; no more than topical therapy required per 12-month period	0
Note: Treatment failure is defined as either disease progression, or less than a 25 percent reduction in the extent and severity of disease after four weeks of prescribed therapy, as documented by medical records.	
* * * * * * *	
7820 Infections of the skin not listed elsewhere (including bacterial, fungal, viral, treponemal and parasitic diseases).	
Evaluate under the General Rating Formula for the Skin.	
7821 Cutaneous manifestations of collagen-vascular diseases not listed elsewhere (including scleroderma, calcinosis cutis, subacute cutaneous lupus erythematosus, and dermatomyositis).	
Evaluate under the General Rating Formula for the Skin.	
7822 Papulosquamous disorders not listed elsewhere (including lichen planus, large or small plaque parapsoriasis, pityriasis lichenoides et varioliformis acuta (PLEVA), lymphomatoid papulosus, mycosis fungoides, and pityriasis rubra pilaris (PRP)).	
Evaluate under the General Rating Formula for the Skin.	
* * * * * * *	
7824 Diseases of keratinization (including icthyoses, Darier's disease, and palmoplantar keratoderma).	
Evaluate under the General Rating Formula for the Skin.	
7825 Urticaria:	
Recurrent documented urticarial attacks occurring four or more times per 12-month period despite continuous immunosuppressive therapy (including, but not limited to, cyclosporine and steroids)	60

	Rating
Recurrent documented urticarial attacks occurring four or more times per 12-month period and requiring intermittent systemic immunosuppressive therapy (including, but not limited to, cyclosporine and steroids) for control	30
At least one of the following	10
Recurrent documented urticarial attacks occurring one to three times per 12-month period, and requiring intermittent systemic immunosuppressive therapy for control, or	
Recurrent documented urticarial attacks occurring four or more times per 12-month period, and requiring treatment with antihistamines or sympathomimetics (including, but not limited to an epipen or intramuscular epinephrine), or	
Without recurrent documented urticarial attacks, but requiring continuous systemic immunosuppressive therapy medication (including, but not limited to, cyclosporine and steroids) for control.	
7826 Vasculitis, primary cutaneous:	
Persistent documented vasculitis episodes refractory to continuous immunosuppressive therapy	60
All of the following	30
Recurrent documented vasculitic episodes occurring four or more times per 12-month period, and	
Requiring intermittent systemic immunosuppressive therapy for control.	
At least one of the following	10
Recurrent documented vasculitic episodes occurring one to three times per 12-month period, and requiring intermittent systemic immunosuppressive therapy for control, or	
Without recurrent documented vasculitic episodes but requiring continuous systemic medication for control.	
Or rate as disfigurement of the head, face, or neck (DC 7800) or scars (DC's 7801, 7802, 7804, or 7805), depending upon the predominant disability.	
7827 Erythema multiforme; Toxic epidermal necrolysis:	
Recurrent mucosal, palmar, or plantar involvement impairing mastication, use of hands, or ambulation occurring four or more times per 12-month period despite ongoing immunosuppresive therapy	60
All of the following	30
Recurrent mucosal, palmar, or plantar involvement not impairing mastication, use of hands, or ambulation occurring four or more times per 12-month period, and	
Requiring intermittent systemic therapy.	
At least one of the following	10
One to three episodes of mucosal, palmar, or plantar involvement not impairing mastication, use of hands, or ambulation occurring per 12-month period AND requiring intermittent systemic therapy, or	
Without recurrent episodes, but requiring continuous systemic medication for control.	
Or rate as disfigurement of the head, face, or neck (DC 7800) or scars (DC's 7801, 7802, 7804, or 7805), depending upon the predominant disability.	
Note: For the purposes of this DC only, systemic therapy may consist of one or more of the following treatment agents: Immunosuppressives, antihistamines, or sympathomimetics.	
7828 Acne:	
Deep acne (deep inflamed nodules and pus-filled cysts) affecting 40 percent or more of the face and neck	30
Deep acne (deep inflamed nodules and pus-filled cysts) affecting less than 40 percent of the face and neck, or; deep acne other than on the face and neck	10
Superficial acne (comedones, papules, pustules) of any extent	0
Or rate as disfigurement of the head, face, or neck (DC 7800) or scars (DC's 7801, 7802, 7804, or 7805), depending upon the predominant disability.	
7829 Chloracne:	
Deep acne (deep inflamed nodules and pus-filled cysts) affecting 40 percent or more of the face and neck	30
Deep acne (deep inflamed nodules and pus-filled cysts) affecting the intertriginous areas (the axilla of the arm, the anogenital region, skin folds of the breasts or between digits)	20
Deep acne (deep inflamed nodules and pus-filled cysts) affecting less than 40 percent of the face and neck; or, deep acne affecting non-intertriginous areas of the body (other than the face and neck)	10
Superficial acne (comedones, papules, pustules) of any extent	0
Or rate as disfigurement of the head, face, or neck (DC 7800) or scars (DC's 7801, 7802, 7804, or 7805), depending upon the predominant disability.	

* * * * * * *

(Authority: 38 U.S.C. 1155)

■ 3. Amend appendix A to part 4, under the entry Sec. 4.118, by:

■ a. Revising the entries for diagnostic codes 7801, 7802, 7805, 7806, 7809, 7813, 7815, 7816, and 7817;

■ b. Removing the entry for 7820–7833;

■ c. Adding entries for diagnostic codes 7820, 7821, 7822, 7823, 7824, 7825, 7826, 7827, 7828, 7829, 7830, 7831, 7832, and 7833.

The revisions and additions read as follows:

APPENDIX A TO PART 4—TABLE OF AMENDMENTS AND EFFECTIVE DATES SINCE 1946

Section	Diagnostic Code No.	
* * *	* *	* *
4.118		
	7801	Criterion July 6, 1950; criterion August 30, 2002; criterion October 23, 2008; title, note 1, note 2 [*effective date of final rule*].

APPENDIX A TO PART 4—TABLE OF AMENDMENTS AND EFFECTIVE DATES SINCE 1946—Continued

Section	Diagnostic Code No.	
	7802	Criterion September 22, 1978; criterion August 30, 2002; criterion October 23, 2008; title, note 1, note 2 [*effective date of final rule*].
*	*	* * * * *
	7805	Criterion October 23, 2008; title [*effective date of final rule]*. General Rating Formula for DCs 7806, 7809, 7813—7816, 7820—7822, and 7824 added [*effective date of final rule]*.
	7806	Criterion September 9, 1975; evaluation August 30, 2002; criterion [*effective date of final rule*].
*	*	* * * * *
	7809	Criterion August 30, 2002; title, criterion [*effective date of final rule*].
*	*	* * * * *
	7813	Criterion August 30, 2002; title, criterion [*effective date of final rule*].
*	*	* * * * *
	7815	Evaluation August 30, 2002; criterion, note [*effective date of final rule*].
	7816	Evaluation August 30, 2002; criterion, note [*effective date of final rule*].
	7817	Evaluation August 30, 2002; title, criterion, note *[effective date of final rule*].
*	*	* * * * *
	7820	Added August 30, 2002; criterion [*effective date of final rule*].
	7821	Added August 30, 2002; title, criterion [*effective date of final rule*].
	7822	Added August 30, 2002; title, criterion [*effective date of final rule*].
	7823	Added August 30, 2002; title, criterion [*effective date of final rule*].
	7824	Added August 30, 2002; criterion [*effective date of final rule*].
	7825	Added August 30, 2002; criterion [*effective date of final rule*].
	7826	Added August 30, 2002; criterion [*effective date of final rule*].
	7827	Added August 30, 2002; criterion [*effective date of final rule*].
	7828	Added August 30, 2002; criterion [*effective date of final rule*].
	7829	Added August 30, 2002; criterion [*effective date of final rule*].
	7830	Added August 30, 2002; title, criterion [*effective date of final rule*].
	7831	Added August 30, 2002; title, criterion [*effective date of final rule*].
	7832	Added August 30, 2002; title, criterion [*effective date of final rule*].
	7833	Added August 30, 2002; title, criterion [*effective date of final rule*].
*	*	* * * * *

■ 4. Amend appendix B to part 4, under the center heading The Skin,, by revising the entries for diagnostic codes 7801, 7802, 7805, 7809, 7813, 7817, 7821, and 7822 to read as follows:

APPENDIX B TO PART 4—NUMERICAL INDEX OF DISABILITIES

Diagnostic Code No.	
*	* * * * * *
	THE SKIN
*	* * * * * *
7801	Burn scar(s) or scar(s) due to other causes, not of the head, face, or neck that are associated with underlying soft tissue damage.
7802	Burn scar(s) or scar(s) due to other causes, not of the head, face, or neck that are not associated with underlying soft tissue damage.
*	* * * * * *
7805	Scars, other; and other effects of scars evaluated under diagnostic codes 7800, 7801, 7802, and 7804.
*	* * * * * *
7809	Discoid lupus erythematosus.
*	* * * * * *
7813	Dermatophytosis.

APPENDIX B TO PART 4—NUMERICAL INDEX OF DISABILITIES—Continued

Diagnostic Code No.	
*	* * * * * *
7817	Erythroderma.
*	* * * * * *
7821	Cutaneous manifestations of collagen-vascular diseases not listed elsewhere (including scleroderma, calcinosis cutis, subacute cutaneous lupus erythematosus, and dermatomyositis).
7822	Papulosquamous disorders not listed elsewhere.
*	* * * * * *

■ 5. Amend appendix C to part 4 by:

■ a. Removing the entry "Cutaneous manifestations of collagen-vascular diseases" and add in its place an entry for "Cutaneous manifestations of collagen-vascular diseases not listed elsewhere (including scleroderma, calcinosis cutis, subacute cutaneous lupus erythematosus, and dermatomyositis)";

■ b. Adding in alphabetical order entries for "Discoid lupus erythematosus", and "Erythroderma"; and

■ c. Revising the entries under "Scars."

The additions and revisions read as follows:

APPENDIX C TO PART 4—ALPHABETICAL INDEX OF DISABILITIES

	Diagnostic Code No.
* * * * * *	*
Cutaneous manifestations of collagen-vascular diseases not listed elsewhere (including scleroderma, calcinosis cutis, subacute cutaneous lupus erythematosus, and dermatomyositis)	7821
* * * * * *	*
Discoid lupus erythematosus	7809
* * * * * *	*
Erythroderma	7817
* * * * * *	*
Scars:	
Burn scar(s) of the head, face, or neck; scar(s) of the head, face, or neck due to other causes; or other disfigurement of the head, face, or neck	7800
Burn scar(s) or scar(s) due to other causes, not of the head, face, or neck that are associated with underlying soft tissue damage	7801
Burn scar(s) or scar(s) due to other causes, not of the head, face, or neck that are not associated with underlying soft tissue damage	7802
Retina	6011
Scars, other; and other effects of scars evaluated under diagnostic codes 7800, 7801, 7802, and 7804	7805
Unstable or painful	7804
* * * * * *	*

[FR Doc. 2016–18695 Filed 8–11–16; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R10–OAR–2016–0394, FRL–9950–55–Region 10]

Approval and Promulgation of Implementation Plans; Washington: Updates to Incorporation by Reference and Miscellaneous Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) proposes to approve State Implementation Plan revisions submitted by the Washington State Department of Ecology (Ecology) on July 11, 2016. The revisions update the incorporation by reference of Federal provisions cited in Ecology's general air quality regulations. The revisions also reflect changes to the primary and secondary National Ambient Air Quality Standards (NAAQS) for ozone, promulgated since Ecology's last update. Ecology also made minor corrections to typographical errors and non-substantive edits for clarity, such as standardizing the citation format.

DATES: Comments must be received on or before September 12, 2016.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R10–OAR–2016–0394 at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Jeff Hunt, Air Planning Unit, Office of Air and Waste (AWT–150), Environmental Protection Agency, Region 10, 1200 Sixth Ave, Suite 900, Seattle, WA 98101; telephone number: (206) 553–0256; email address: *hunt.jeff@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document wherever "we," "us," or "our" is used, it is intended to refer to the EPA.

Table of Contents

I. Background
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I. Background

Section 110 of the Clean Air Act (CAA) governs the process by which a state submits air quality requirements to the EPA for approval into the State Implementation Plan (SIP). The SIP is a state's plan to implement, maintain and enforce the NAAQS. Ecology's general air quality regulations are set forth at Chapter 173–400 of the Washington Administrative Code (WAC). The EPA last approved changes to Chapter 173–400 WAC on April 29, 2015, which incorporates by reference certain Federal regulations, as of July 1, 2012 (80 FR 23721). Washington also adopts and implements changes to the NAAQS under Chapter 173–476 WAC, which the EPA last approved on March 4, 2014 (79 FR 12078). On July 11, 2016, Washington submitted a request to update Chapters 173–400 and 173–476 WAC in the SIP, with revised Federal citations as of January 1, 2016.

II. Analysis of Rule Updates

Chapter 173–400 WAC

In order to streamline updates to Chapter 173–400 WAC and the Washington SIP, Ecology created a new section, WAC 173–400–025 *Adoption of Federal Rules,* which states, "Federal rules mentioned in this rule are adopted as they exist on January 1, 2016. Adopted or adopted by reference means the federal rule applies as if it was copied into this rule." As part of this process, Ecology modified other sections of Chapter 173–400 WAC to remove citations to specific Federal regulation adoption dates, in order to rely on WAC 173–400–025. Ecology also corrected minor typographical errors, standardized references, and consistently formatted Federal citations. A redline/strikeout of the changes is included in the State's submittal, contained in the docket for this action. We reviewed these changes and are proposing to approve the revisions.

One outcome of Ecology's update to Chapter 173–400 WAC relates to the Prevention of Significant Deterioration (PSD) permitting program for major stationary sources in attainment and unclassifiable areas. The Washington SIP, at WAC 173–400–720(4)(a)(vi), generally incorporates by reference the Federal PSD regulations contained in 40 CFR 52.21, with certain exceptions (80 FR 23721, April 29, 2015). As part of our April 29, 2015 final action on WAC 173–400–720(4)(a)(vi) we excluded the incorporation by reference of 40 CFR 52.21(b)(49)(v), 40 CFR 52.21(i)(5)(i), and 40 CFR 52.21(k)(2), as the Federal rules existed on July 1, 2012. These citations relate to Federal greenhouse gas, and fine particulate matter significant monitoring concentration and significant impact level provisions vacated by Federal courts after July 1, 2012 (see our proposed rulemaking for a full discussion, 80 FR 838, January 7, 2015, at page 842). After the court vacated the provisions, the EPA removed the provisions from 40 CFR 52.21 on December 9, 2013 (78 FR 73698) and August 19, 2015 (80 FR 50199). Ecology's revised incorporation by reference of these Federal regulations as of January 1, 2016, captures the EPA's removal of the vacated provisions. We are proposing to fully approve WAC 173–400–720(4)(a)(vi) because it meets current Federal requirements and is consistent with the court decisions. All other exceptions to our approval of Chapter 173–400 WAC remain unchanged since our April 29, 2015 final action.

Ecology also requested that the EPA update the Chapter 173–400 WAC citations for the Benton Clean Air Agency (BCAA) jurisdiction consistent with the exceptions noted in our November 17, 2015 final approval (80 FR 71695). As discussed in the proposed rulemaking for that action, BCAA does not implement WAC provisions related to the PSD program under WAC 173–400–116 and 173–400–700 through 173–400–750 (80 FR 55280, September 15, 2015, at page 55283). Also, as described in the proposed rulemaking for that action, BCAA local requirements contained in Regulation I, section 4.02 apply in lieu of the WAC provisions contained in WAC 173–400–040(4), WAC 173–400–040(9)(a), and WAC 173–400–040(9)(b). The EPA is therefore proposing to approve the update to Chapter 173–400 WAC for BCAA's jurisdiction consistent with the exceptions noted above. The EPA is also proposing to revise the visibility protection Federal Implementation Plan contained in 40 CFR 52.2498 to reflect the approval of WAC 173–400–117 *Special Protection Requirements for Federal Class I Areas* for sources within BCAA's jurisdiction.

Chapter 173–476 WAC

The EPA last approved changes to Chapter 173–476 WAC on March 4, 2014, which contained all promulgated Federal NAAQS in existence at that time (79 FR 12078). In 2015, the EPA revised 40 CFR part 50 to include revised primary and secondary 8-hour ambient air quality standards for ozone at 0.070 parts per million (80 FR 65292, Oct. 26, 2015). Ecology's revision to Chapter 173–476 includes this update to the ozone standards and the interpretation method contained in 40 CFR part 50, Appendix U. We are proposing to approve the revisions to Chapter 173–476 WAC as meeting current Federal requirements.

III. Proposed Action

We are proposing to approve and incorporate by reference in the Washington SIP at 40 CFR 52.2470(c) the following revisions to Chapters 173–400 and 173–476 WAC as shown in the table below.

State citation	Title/subject	State effective date	Explanations
40 CFR 52.2470(c), TABLE 1—REGULATIONS APPROVED STATEWIDE			
Washington Administrative Code, Chapter 173–476—Ambient Air Quality Standards			
173–476–020	Applicability	07/01/16	
173–476–150	Ambient Air Quality Standard for Ozone	07/01/16	
173–476–900	Appendix A. Table of Standards	07/01/16	
40 CFR 52.2470(c), TABLE 2—ADDITIONAL REGULATIONS APPROVED FOR WASHINGTON DEPARTMENT OF ECOLOGY (ECOLOGY) DIRECT JURISDICTION			
Washington Administrative Code, Chapter 173–400—General Regulations for Air Pollution Sources			
173–400–025	Adoption of Federal Rules	07/01/16	
173–400–040	General Standards for maximum Emissions	07/01/16	Except: 173–400–040(2)(c); 173–400–040(2)(d); 173–400–040(3); 173–400–040(5); 173–400–040(7), second paragraph.
173–400–050	Emission Standards for Combustion and Incineration Units.	07/01/16	Except: 173–400–050(2) and 173–400–050(4) through (6).
173–400–060	Emission Standards for General Process Units	07/01/16	
173–400–070	Emission Standards for Certain Source Categories	07/01/16	Except: 173–400–070(7); 173–400–070(8).
173–400–105	Records, Monitoring, and Reporting	07/01/16	
173–400–111	Processing Notice of Construction Applications for Sources, Stationary Sources and Portable Sources.	07/01/16	Except: 173–400–111(3)(h); The part of 173–400–111(8)(a)(v) that says, • “and 173–460–040,”; 173–400–111(9).
173–400–116	Increment Protection	07/01/16	
173–400–171	Public Notice and Opportunity for Public Comment	07/01/16	Except: The part of 173–400–171(3)(b) that says, • “or any increase in emissions of a toxic air pollutant above the acceptable source impact level for that toxic air pollutant as regulated under chapter 173–460 WAC”; 173–400–171(12).
173–400–710	Definitions	07/01/16	
173–400–720	Prevention of Significant Deterioration (PSD)	07/01/16	Except: 173–400–720(4)(a)(i through iv) and 173–400–720(4)(b)(iii)(C).
173–400–730	Prevention of Significant Deterioration Application Processing Procedures.	07/01/16	
173–400–740	PSD Permitting Public Involvement Requirements	07/01/16	
173–400–810	Major Stationary Source and Major Modification Definitions.	07/01/16	
173–400–830	Permitting Requirements	07/01/16	
173–400–840	Emission Offset Requirements	07/01/16	
173–400–850	Actual Emissions Plantwide Applicability Limitation (PAL).	07/01/16	
40 CFR 52.2470(c), TABLE 4—ADDITIONAL REGULATIONS APPROVED FOR BENTON CLEAN AIR AGENCY (BCAA) JURISDICTION			
173–400–025	Adoption of Federal Rules	07/01/16	
173–400–040	General Standards for Maximum Emissions	07/01/16	Except: 173–400–040(2)(c); 173–400–040(2)(d); 173–400–040(3); 173–400–040(4); 173–400–040(5); 173–400–040(7), second paragraph; 173–400–040(9)(a); 173–400–040(9)(b).
173–400–050	Emission Standards for Combustion and Incineration Units.	07/01/16	Except: 173–400–050(2) and 173–400–050(4) through (6).
173–400–060	Emission Standards for General Process Units	07/01/16	
173–400–070	Emission Standards for Certain Source Categories	07/01/16	Except: 173–400–070(7); 173–400–070(8).
173–400–105	Records, Monitoring, and Reporting.	07/01/16	
173–400–111	Processing Notice of Construction Applications for Sources, Stationary Sources and Portable Sources.	07/01/16	Except: 173–400–111(3)(h); The part of 173–400–111(8)(a)(v) that says, • “and 173–460–040,”; 173–400–111(9).
173–400–171	Public Notice and Opportunity for Public Comment	07/01/16	Except: The part of 173–400–171(3)(b) that says, • “or any increase in emissions of a toxic air pollutant above the acceptable source impact level for that toxic air pollutant as regulated under chapter 173–460 WAC”; 173–400–171(12).
173–400–810	Major Stationary Source and Major Modification Definitions.	07/01/16	
173–400–830	Permitting Requirements	07/01/16	
173–400–840	Emission Offset Requirements	07/01/16	
173–400–850	Actual Emissions Plantwide Applicability Limitation (PAL).	07/01/16	

We are also proposing to approve, but not incorporate by reference, the revised version of WAC 173–400–260 *Conflict of Interest,* state effective July 1, 2016. Consistent with prior actions on the Washington SIP, the EPA reviews and approves state and local clean air agency submissions to ensure they provide adequate enforcement authority and other general authority to implement and enforce the SIP. However, regulations describing such agency enforcement and other general authority are typically not incorporated by reference so as to avoid potential conflict with the EPA's independent authorities. Therefore, we propose to approve, WAC 173–400–260 into the Washington SIP, but not incorporate the provision by reference.

IV. Incorporation by Reference

In this rule, the EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference the regulations in the table in section III above. The EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and/or at the EPA Region 10 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this proposed action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land in Washington except as specifically noted below and is also not approved to apply in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). Washington's SIP is approved to apply on non-trust land within the exterior boundaries of the Puyallup Indian Reservation, also known as the 1873 Survey Area. Under the *Puyallup Tribe of Indians Settlement Act of 1989,* 25 U.S.C. 1773, Congress explicitly provided state and local agencies in Washington authority over activities on non-trust lands within the 1873 Survey Area. Consistent with EPA policy, the EPA provided a consultation opportunity to the Puyallup Tribe in a letter dated July 13, 2016.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: August 1, 2016.

Michelle L. Pirzadeh,

Acting Regional Administrator, Region 10.

[FR Doc. 2016–19031 Filed 8–11–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2016–0366; FRL–9950–36–Region 8]

Approval and Promulgation of State Implementation Plan Revisions to Primary Air Quality Standards, Minor Source Baseline Date, Incorporation by Reference, and 2008 Ozone NAAQS Infrastructure Requirements for CAA Section 110(a)(2)(C) and (D)(i)(II); Wyoming

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve State Implementation Plan (SIP) revisions submitted by the State of Wyoming on May 28, 2015 and November 6, 2015. The amendments update the version of the Code of Federal Regulations (CFR) incorporated by reference into the rules of the State of Wyoming for Chapter 2, Section 12; Chapter 3, General Emission Standards, Section 9; and Chapter 6, Prevention of Significant Deterioration, Section 4. The May 28, 2015 submittal updates a citation to a **Federal Register** article (*i.e.,* **Federal Register** notice) under the definition of "tpy CO_2 equivalent emissions (CO_2e)," and lists a new minor source baseline date for fine particulate. The State also proposes to update the primary air quality standards for particulate matter ($PM_{2.5}$) to reflect federal updates that went into effect in January 2013. The updated primary $PM_{2.5}$ standard is 12 micrograms per cubic meter (μg/m³) annual arithmetic mean concentration, which is lowered from its previous level of 15 μg/m³. The EPA is also proposing approval of portions of the State's February 6, 2014 2008 ozone National Ambient Air Quality Standards (NAAQS) infrastructure certification regarding prevention of significant deterioration (PSD) and the good neighbor provision. The EPA is not taking action on the Chapter 6, Permitting Requirements, Section 14 portion of the May 24, 2012 submittal because it has been superseded by a November 6, 2015 submittal (81 FR 35271). The EPA is not

taking action on a May 24, 2012 submittal or a March 8, 2013 submittal because they have been superseded by the May 28, 2015 submittal.

DATES: Written comments must be received on or before September 12, 2016.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R08–OAR–2016–0366, at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.,) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Jody Ostendorf, Air Program, U.S. Environmental Protection Agency (EPA), Region 8, Mail Code 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129, (303) 312–7814, *ostendorf.jody@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

What should I consider as I prepare my comments for the EPA?

1. *Submitting Confidential Business Information (CBI).* Do not submit CBI to the EPA through *http://www.regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on a disk or CD ROM that you mail to the EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** volume, date, and page number);
- Follow directions and organize your comments;
- Explain why you agree or disagree;
- Suggest alternatives and substitute language for your requested changes;
- Describe any assumptions and provide any technical information and/or data that you used;
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced;
- Provide specific examples to illustrate your concerns, and suggest alternatives;
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats; and,
- Make sure to submit your comments by the comment period deadline identified.

II. Analysis of the State Submittals

In this proposed rulemaking, we are proposing to approve three submittals into Wyoming's SIP.

May 28, 2015 Submittals

The first May 28, 2015 submittal updates Chapter 3, General Emission Standards, Section 9, Incorporation by reference, to adopt by reference the July 1, 2013 Code of Federal Regulations. This submittal supersedes previously submitted updates to Section 9, Incorporation by reference. The EPA proposes to approve this submittal.

The second May 28, 2015 submittal updates Chapter 6, Section 4, Prevention of significant deterioration (PSD) program. The submittal updates a citation to a **Federal Register** article (*i.e.,* **Federal Register** notice) under the definition of "tpy CO_2 equivalent emissions (CO_2e)." The article is available for public inspection and can be obtained online at *http://www.gpo.gov/fdsys/pkg/FR-2013-11-29/pdf/2013-27996.pdf* or at a cost from the Department of Environmental Quality, Division of Air Quality, Cheyenne Office. Contact information for the Cheyenne Office can be obtained at: *http://deq.state.wy.us.* The EPA is proposing to approve this update.

The submittal also lists a new minor source baseline date of December 12, 2012 for fine particulate for Sweetwater County. On October 20, 2010, the EPA published a final rulemaking titled "Prevention of Significant Deterioration (PSD) for $PM_{2.5}$—Increments, Significant Impact Levels (SILs) and Significant Monitoring Concentration" (75 FR 64864). This rulemaking revised 40 CFR 51.166(b)(14)(ii) (Definition of Minor Source Baseline Date) to add a trigger date of October 20, 2011 for $PM_{2.5}$. A minor source baseline date means the earliest date after the trigger date on which a major stationary source or a major modification subject to 40 CFR 52.21, or 40 CFR 51.166, submits a complete permit application under the relevant PSD regulations. The EPA is proposing to approve Sweetwater County's minor source baseline date of December 12, 2012.

The submittal also proposed to update Chapter 6, Section 14, Incorporation by reference, to adopt by reference from the July 1, 2013 CFR. This submittal and previously submitted updates to Section 14, Incorporation by reference have been superseded by a November 6, 2015 rulemaking (81 FR 35271). The EPA is not acting on any updates to Chapter 6, Section 14, Incorporation by reference.

November 6, 2015 Submittal

The November 6, 2015 submittal proposes to revise Chapter 2, Section 2, Ambient standards for particulate matter, which establishes standards of ambient air quality for particulate matter as necessary to protect public health and welfare. This revision updates the primary ambient air quality standards for $PM_{2.5}$ to reflect federal updates that went into effect in January 2013. The updated primary $PM_{2.5}$ standard is 12 $\mu g/m^3$ annual arithmetic mean concentration, which is lowered from its previous level of 15 $\mu g/m^3$. The EPA proposes to approve this revision.

The submittal also proposes to update Chapter 12, Incorporation by reference, to adopt by reference the July 1, 2014 CFR. This submittal supersedes previously submitted updates to the Chapter 12, Incorporation by reference. The EPA proposes to approve this submittal.

February 6, 2014, 2008 Ozone NAAQS Infrastructure Certification

On March 12, 2008, the EPA promulgated a new NAAQS for ozone, revising the levels of the primary and secondary 8-hour ozone standards from 0.08 parts per million (ppm) to 0.075 ppm (73 FR 16436, March 27, 2008).

Under Sections 110(a)(1) and (2) of the CAA, states are required to submit infrastructure SIPs to ensure their SIPs provide for implementation, maintenance and enforcement of the NAAQS. These submissions must contain any revisions needed for meeting the applicable SIP requirements of Section 110(a)(2), or certifications that their existing SIP already meet those requirements. The EPA is acting upon the certification from Wyoming that addresses the infrastructure requirements of CAA Sections 110(a)(1) and 110(a)(2)(C) and (D)(i)(II) prong 3 for the 2008 ozone NAAQS. The requirement for states to make a SIP submission of this type arises out of CAA Section 110(a)(1). Pursuant to Section 110(a)(1), states must make SIP submissions "within three years (or such shorter period as the Administrator may prescribe) after the promulgation of a national primary ambient air quality standard (or any revision thereof)," of such NAAQS. The statute directly imposes on states the duty to make these SIP submissions, and the requirement to make the submissions is not conditioned upon the EPA taking any action other than promulgating a new or revised NAAQS.

The list of required elements provided in Section 110(a)(2) contains a wide variety of disparate provisions, some of which pertain to required legal authority, substantive program provisions, and both authority and substantive programs. The EPA does not believe that an action on a state's infrastructure SIP submission is necessarily the appropriate type of action to address possible deficiencies in a state's existing SIP. These issues include: (i) Existing provisions related to excess emissions from sources during periods of startup, shutdown, or malfunction (SSM) that may be contrary to the CAA and the EPA's policies addressing such excess emissions; (ii) existing provisions related to "director's variance" or "director's discretion" that may be contrary to the CAA because they purport to allow revisions to SIP-approved emissions limits while limiting public process or not requiring further approval by the EPA; and (iii) existing provisions for PSD programs that may be inconsistent with current requirements of the EPA's "Final NSR Improvement Rule," 67 FR 80186, Dec. 31, 2002, as amended by 72 FR 32526, June 13, 2007 ("NSR Reform").

CAA Section 110(a)(1) provides the procedural and timing requirements for SIP submissions after a new or revised NAAQS is promulgated. Section 110(a)(2) lists specific elements the SIP must contain or satisfy. Two elements identified in section 110(a)(2) are not governed by the three year submission deadline of Section 110(a)(1) and are therefore not addressed in this action. These elements relate to part D of Title I of the CAA, and submissions to satisfy them are not due within three years after promulgation of a new or revised NAAQS, but rather are due at the same time nonattainment area plan requirements are due under Section 172. The two elements are: (1) Section 110(a)(2)(C) to the extent it refers to permit programs (known as "nonattainment NSR") required under part D; and (2) Section 110(a)(2)(I), pertaining to the nonattainment planning requirements of part D. As a result, this action does not address infrastructure elements related to the nonattainment NSR portion of Section 110(a)(2)(C) or related to 110(a)(2)(I). Furthermore, the EPA interprets the CAA Section 110(a)(2)(J) provision on visibility as not being triggered by a new NAAQS because the visibility requirements in part C, title 1 of the CAA are not changed by a new NAAQS.

In this action, the EPA is addressing 110(a)(2)(C), programs for enforcement of control measures and for construction or modification of stationary sources, and 110(a)(2)(D)(i)(II) element 3 for the 2008 ozone NAAQS. The EPA is addressing all other elements for the 2008 ozone NAAQS in a separate rulemaking.

The Wyoming Department of Environmental Quality (Department or WDEQ) submitted certification of Wyoming's infrastructure SIP for the 2008 ozone NAAQS on February 6, 2014. Wyoming's infrastructure certification demonstrates how the State, where applicable, has plans in place that meet the requirements of Section 110 for the 2008 ozone NAAQS. The Wyoming Air Quality Standards and Regulations (WAQSR) referenced in the State's submittal are publicly available at *http://soswy.state.wy.us/Rules/default.aspx.* Air pollution control regulations and statutes that have been previously approved by the EPA and incorporated into the Wyoming SIP can be found at 40 CFR 52.2620.

1. *Program for enforcement of control measures:* Section 110(a)(2)(C) requires SIPs to "include a program to provide for the enforcement of the measures described in subparagraph (A), and regulation of the modification and construction of any stationary source within the areas covered by the plan as necessary to assure that [NAAQS] are achieved, including a permit program as required in parts C and D."

To generally meet the requirements of Section 110(a)(2)(C), the State is required to have SIP-approved PSD, nonattainment NSR, and minor NSR permitting programs that are adequate to implement the 2008 ozone NAAQS. As explained elsewhere in this action, the EPA is not evaluating nonattainment related provisions, such as the nonattainment NSR program required by part D of the Act. The EPA is evaluating the State's PSD program as required by part C of the Act, and the State's minor NSR program as required by Section 110(a)(2)(C).

Enforcement of Control Measures Requirement

Wyoming's Rule (02) II, Legal Authority, which the EPA approved into Wyoming's SIP,[1] allows the State to enforce applicable laws, regulations, and standards; to seek injunctive relief; and to provide authority to prevent construction, modification, or operation of any stationary source at any location where emissions from such source will prevent the attainment or maintenance of a national standard or interfere with prevention of significant deterioration requirements.

PSD Requirements

With respect to Element (C), the EPA interprets the CAA to require each state to make an infrastructure SIP submission for a new or revised NAAQS demonstrating that the air agency has a complete PSD permitting program meeting the current requirements for all regulated NSR pollutants. The requirements of Element D(i)(II) may also be satisfied by demonstrating the air agency has a complete PSD permitting program that correctly addresses all regulated NSR pollutants. Wyoming has shown that it currently has a PSD program in place that covers all regulated NSR pollutants, including greenhouse gases (GHGs).

On July 25, 2011 (76 FR 44265), we approved a revision to the Wyoming PSD program that addressed the PSD requirements of the Phase 2 Ozone Implementation Rule promulgated on November 29, 2005 (70 FR 71612). As a result, the approved Wyoming PSD program meets the current requirements for ozone.

With respect to GHG's, on June 23, 2014, the United States Supreme Court addressed the application of PSD permitting requirements to GHG emissions. *Utility Air Regulatory Group* v. *Environmental Protection Agency,* 134 S.Ct. 2427 (2014). The Supreme Court held that the EPA may not treat GHGs as an air pollutant for purposes of determining whether a source is a major source required to obtain a PSD permit.

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[1] *See* 40 CFR 52.2620(e), Rule No. (02) II; 41 FR 36652 (Aug. 31, 1976) (approving Wyoming's revisions to its SIP).

The Court also held that the EPA could continue to require that PSD permits, otherwise required based on emissions of pollutants other than GHGs (anyway sources) contain limitations on GHG emissions based on the application of Best Available Control Technology (BACT).

In accordance with the Supreme Court decision, on April 10, 2015, the U.S. Court of Appeals for the District of Columbia Circuit (the D.C. Circuit) in *Coalition for Responsible Regulation* v. *EPA,* 606 F. App'x. 6, at *7–8 (D.C. Cir. April 10, 2015), issued an amended judgment vacating the regulations that implemented Step 2 of the EPA's PSD and Title V Greenhouse Gas Tailoring Rule, but not the regulations that implement Step 1 of that rule. Step 1 of the Tailoring Rule covers sources that are required to obtain a PSD permit based on emissions of pollutants other than GHGs. Step 2 applied to sources that emitted only GHGs above the thresholds triggering the requirement to obtain a PSD permit. The amended judgment preserves, without the need for additional rulemaking by the EPA, the application of the BACT requirement to GHG emissions from Step 1 or "anyway" sources.[2] With respect to Step 2 sources, the D.C. Circuit's amended judgment vacated the regulations at issue in the litigation, including 40 CFR 51.166(b)(48)(v), "to the extent they require a stationary source to obtain a PSD permit if greenhouse gases are the only pollutant (i) that the source emits or has the potential to emit above the applicable major source thresholds, or (ii) for which there is a significant emission increase from a modification."

The EPA is planning to take additional steps to revise the federal PSD rules in light of the Supreme Court and subsequent D.C. Circuit opinion. Some states have begun to revise their existing SIP-approved PSD programs in light of these court decisions, and some states may prefer not to initiate this process until they have more information about the planned revisions to the EPA's PSD regulations. The EPA is not expecting states to have revised their PSD programs in anticipation of the EPA's planned actions to revise its PSD program rules in response to the court decisions.

At present, the EPA has determined that Wyoming's SIP is sufficient to satisfy Elements (C) and (D)(i)(II) prong 3 with respect to GHGs. This is because the PSD permitting program previously approved by the EPA into the SIP continues to require that PSD permits issued to "anyway sources" contain limitations on GHG emissions based on the application of BACT. The EPA most recently approved revisions to Wyoming's PSD program on December 6, 2013 (78 FR 73445). The approved Utah PSD permitting program still contains some provisions regarding Step 2 sources that are no longer necessary in light of the Supreme Court decision and D.C. Circuit amended judgment. Nevertheless, the presence of these provisions in the previously-approved plan does not render the infrastructure SIP submission inadequate to satisfy Elements (C) and (D)(i)(II). The SIP contains the PSD requirements for applying the BACT requirement to greenhouse gas emissions from "anyway sources" that are necessary at this time. The application of those requirements is not impeded by the presence of other previously-approved provisions regarding the permitting of Step 2 sources. Accordingly, the Supreme Court decision and subsequent D.C. Circuit judgment do not prevent the EPA's approval of Wyoming's infrastructure SIP as to the requirements of Elements (C) and (D)(i)(II) prong 3.

Finally, we evaluate the PSD program with respect to current requirements for $PM_{2.5}$. In particular, on May 16, 2008, the EPA promulgated the rule, "Implementation of the New Source Review Program for Particulate Matter Less Than 2.5 Micrometers ($PM_{2.5}$)" (73 FR 28321) (2008 Implementation Rule). On October 20, 2010 the EPA promulgated the rule, "Prevention of Significant Deterioration (PSD) for Particulate Matter Less Than 2.5 Micrometers ($PM_{2.5}$)—Increments, Significant Impact Levels (SILs) and Significant Monitoring Concentration (SMC)" (75 FR 64864). The EPA regards adoption of these $PM_{2.5}$ rules as a necessary requirement when assessing a PSD program for the purposes of Element (C).

On January 4, 2013, the U.S. Court of Appeals, in *Natural Resources Defense Council* v. *EPA,* 706 F.3d 428 (D.C. Cir.), issued a judgment that remanded the EPA's 2007 and 2008 rules implementing the 1997 $PM_{2.5}$ NAAQS. The court ordered the EPA to "repromulgate these rules pursuant to Subpart 4 consistent with this opinion." *Id.* at 437. Subpart 4 of part D, Title 1 of the CAA establishes additional provisions for particulate matter nonattainment areas.

The 2008 Implementation Rule addressed by *Natural Resources Defense Council,* "Implementation of New Source Review (NSR) Program for Particulate Matter Less Than 2.5 Micrometers ($PM_{2.5}$)," (73 FR 28321, May 16, 2008), promulgated NSR requirements for implementation of $PM_{2.5}$ in nonattainment areas (nonattainment NSR) and attainment/unclassifiable areas (PSD). As the requirements of Subpart 4 only pertain to nonattainment areas, the EPA does not consider the portions of the 2008 Implementation Rule that address requirements for $PM_{2.5}$ attainment and unclassifiable areas to be affected by the court's opinion. Moreover, the EPA does not anticipate the need to revise any PSD requirements promulgated in the 2008 Implementation Rule in order to comply with the court's decision. Accordingly, the EPA's proposed approval of Wyoming's infrastructure SIP as to Elements (C) or (D)(i)(II) prong 3 with respect to the PSD requirements promulgated by the 2008 Implementation rule does not conflict with the court's opinion.

The court's decision with respect to the nonattainment NSR requirements promulgated by the 2008 Implementation Rule also does not affect the EPA's action on the present infrastructure action. The EPA interprets the Act to exclude nonattainment area requirements, including requirements associated with a nonattainment NSR program, from infrastructure SIP submissions due three years after adoption or revision of a NAAQS. Instead, these elements are typically referred to as nonattainment SIP or attainment plan elements, which would be due by the dates statutorily prescribed under subpart 2 through 5 under part D, extending as far as 10 years following designations for some elements.

The second PSD requirement for $PM_{2.5}$ is contained in the EPA's October 20, 2010 rule, "Prevention of Significant Deterioration (PSD) for Particulate Matter Less Than 2.5 Micrometers ($PM_{2.5}$)—Increments, Significant Impact Levels (SILs) and Significant Monitoring Concentration (SMC)" (75 FR 64864). The EPA regards adoption of the $PM_{2.5}$ increments as a necessary requirement when assessing a PSD program for the purposes of Element (C). On July 25, 2011 (76 FR 44265), the EPA approved SIP revisions that revised Wyoming's PSD program which incorporated the 2008 Implementation Rule. The EPA approved revisions to reflect the 2010 $PM_{2.5}$ Increment Rule on December 6, 2013 (78 FR 73445). Therefore, Wyoming's SIP approved PSD program meets current requirements for $PM_{2.5}$. As a result, the EPA is proposing to approve Wyoming's infrastructure SIP for the 2008 ozone NAAQS with respect to the requirement in Section

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[2] *See* 77 FR 41066 (July 12, 2012) (rulemaking for definition of "anyway" sources).

110(a)(2)(C) to include a permit program in the SIP as required by part C of the Act.

Minor NSR

The State has a SIP-approved minor NSR program, adopted under Section 110(a)(2)(C) of the Act. The minor NSR program is found in Chapter 6, Section 2 of the WAQSR. The EPA previously approved Wyoming's minor NSR program into the SIP (at that time as Chapter 1, Section 21), and has subsequently approved revisions to the program, and at those times there were no objections to the provisions of this program. (See, for example, 47 FR 5892, February 9, 1982). Since then, the State and the EPA have relied on the State's existing minor NSR program to assure that new and modified sources not captured by the major NSR permitting program do not interfere with attainment and maintenance of the NAAQS.

The EPA is proposing to approve Wyoming's infrastructure SIP for the 2008 ozone NAAQS with respect to the general requirement in Section 110(a)(2)(C) to include a program in the SIP that regulates the enforcement, modification, and construction of any stationary source as necessary to assure that the NAAQS are achieved.

2. *Interstate Transport:* CAA Section 110(a)(2)(D)(i)(I) requires SIPs to include provisions prohibiting any source or other type of emissions activity in one state from emitting any air pollutant in amounts that will contribute significantly to nonattainment, or interfere with maintenance, of the NAAQS in another state (known as the "good neighbor" provision). The two provisions of this section are referred to as prong 1 (significant contribution to nonattainment) and prong 2 (interfere with maintenance). Section 110(a)(2)(D)(i)(II) requires SIPs to contain adequate provisions to prohibit emissions that will interfere with measures required to be included in the applicable implementation plan for any other state under part C to prevent significant deterioration of air quality (prong 3) or to protect visibility (prong 4). In this action, the EPA is addressing prong 3 with regard to the 2008 ozone NAAQS. The EPA will address all other transport prongs in a separate rulemaking.

With regard to the PSD portion of CAA Section 110(a)(2)(D)(i)(II), this requirement may be met by a state's confirmation in an infrastructure SIP submission that new major sources and major modifications in the state are subject to a comprehensive EPA approved PSD permitting program in the SIP that applies to all regulated new source review (NSR) pollutants and that satisfies the requirements of the EPA's PSD implementation rules.[3] As noted in the discussion for infrastructure Element (C) earlier in this notice, the EPA is proposing to approve CAA Section 110(a)(2) Element (C) for Utah's infrastructure SIP for the 2008 ozone NAAQS with respect to PSD requirements. As discussed in detail in that section, Wyoming's SIP meets the current PSD-related requirements of Section 110(a)(2)(C).

In-state sources not subject to PSD for a particular NAAQS because they are in a nonattainment area for that standard may also have the potential to interfere with PSD in an attainment or unclassifiable area of another state.[4] One way a state may satisfy prong 3 with respect to these sources is by citing an air agency's EPA-approved nonattainment NSR provisions addressing any pollutants for which the state has designated nonattainment areas. Wyoming has a SIP-approved nonattainment NSR program which ensures regulation of major sources and major modifications in nonattainment areas, and therefore satisfies prong 3 with regard to this requirement.[5]

The EPA is proposing to approve the infrastructure SIP submission with regard to the requirements of prong 3 of Section 110(a)(2)(D)(i)(II) for the 2008 Ozone NAAQS.

III. What action is the EPA taking today?

The EPA is proposing to approve State Implementation Plan (SIP) revisions submitted by the State of Wyoming on May 28, 2015 and November 6, 2015. The amendments update the version of the CFR incorporated by reference into the rules of the State of Wyoming for Chapter 2, Ambient Standards for Particulate Matter, Section 12; and Chapter 3, General Emission Standards, Section 9. The EPA is also proposing to approve updates to a citation to a **Federal Register** article (*i.e.,* **Federal Register** notice) under the definition of "tpy CO_2 equivalent emissions (CO_2e)," and a new minor source baseline date for fine particulate for Sweetwater County of December 12, 2012 into WAQSR Chapter 6, Section 4. The EPA proposes to approve an update to the primary air quality standards for particulate matter $(PM)_{2.5}$ that reflects federal updates that went into effect in January 2013 into WAQSR Chapter 2, Section 2. The EPA proposes to approve infrastructure elements (C) and (D)(i)(II)prong for the 2008 ozone NAAQS from the State's February 6, 2014 certification. Finally, the EPA is not taking action on the Chapter 6, Permitting Requirements, Section 14 portion of the May 24, 2012 submittal, the March 8, 2013 submittal, or the May 28, 2015 submittal because they have been superseded by a November 6, 2015 submittal (81 FR 35271).

IV. Incorporation by Reference

In this rule, the EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference the Administrative Rules of Wyoming pertaining to General Emission Standards, Prevention of Significant Deterioration and Ambient Standards for $PM_{2.5,}$ as discussed in Section II. The EPA has made, and will continue to make, these documents generally available electronically through *www.regulations.gov* and/or at the EPA Region 8 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);

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[3] See EPA's "Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act Sections 110(a)(1) and (2)," September 13, 2013, at 31.

[4] Id. at 31.

[5] See WAQSR Chapter 6, Section 13.

- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: July 28, 2016.

Shaun L. McGrath,

Regional Administrator, Region 8.

[FR Doc. 2016–18869 Filed 8–11–16; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2016–0016; FRL–9950–37–Region 8]

Approval and Promulgation of Air Quality Implementation Plans; State of Colorado; Motor Vehicle Inspection and Maintenance, Clean Screen Program and the Low Emitter Index, On-Board Diagnostics, and Associated Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing approval of three State Implementation Plan (SIP) revisions submitted by the State of Colorado. The revisions involve amendments to Colorado's Regulation Number 11 "Motor Vehicle Emissions Inspection Program." The revisions address the implementation of the Low Emitter Index component of Regulation No. 11's Clean Screen Program, the implementation of the On-Board Diagnostics component of Regulation No. 11, and several other associated revisions. The EPA is proposing approval of these SIP revisions in accordance with the requirements of section 110 of the Clean Air Act (CAA).

DATES: Written comments must be received on or before September 12, 2016.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R08–OAR–2016–0016 at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from regulations.gov. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.,) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Tim Russ, Air Program, EPA, Region 8, Mailcode 8P–AR, 1595 Wynkoop, Denver, Colorado 80202–1129, (303) 312–6479, *russ.tim@epa.gov.*

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VI. EPA's Evaluation of the State's 2013 Revisions to Part A, Part C, Appendix A, and Appendix B
VII. Conclusion
VIII. Consideration of Section 110(l) of the Clean Air Act
IX. Proposed Action
X. Incorporation by Reference
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I. General Information

What should I consider as I prepare my comments for the EPA?

1. Submitting Confidential Business Information (CBI). Do not submit CBI to the EPA through *http://www.regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to the EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** volume, date, and page number);
- Follow directions and organize your comments;
- Explain why you agree or disagree;
- Suggest alternatives and substitute language for your requested changes;

- Describe any assumptions and provide any technical information and/or data that you used;
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced;
- Provide specific examples to illustrate your concerns, and suggest alternatives;
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats; and,
- Make sure to submit your comments by the comment period deadline identified.

II. Background

In this action, the EPA is proposing approval of SIP revisions to Regulation No. 11 contained in three submittals from Colorado. The State's submittals were dated June 11, 2008, March 15, 2013, and March 3, 2014. Much of the content of the revisions involved minor updates to several sections of Regulation No. 11 and deletion of obsolete language. The following background discussion involves those revisions of greater significance:

a.) Colorado's 2007 Revisions to Regulation No. 11 for the Implementation of the Low Emitter Index (LEI) Portion of the Clean Screen Program Contained in Regulation No. 11

Colorado's Regulation No. 11 (hereafter "Reg. No. 11") addresses the implementation of the State's motor vehicle inspection and maintenance (I/M) program. The I/M program consists of an "enhanced" component that utilizes a dynamometer-based EPA IM240 test for 1982 and newer light-duty gasoline vehicles [1] and a two-speed idle test (TSI) [2] for 1981 and older light-duty gasoline vehicles. To improve motorist convenience and reduce program implementation costs, the State also administers a remote sensing-based "Clean Screen" program component of the I/M program. Remote sensing is a method for measuring vehicle emissions, while simultaneously photographing the license plate, when a vehicle passes through infrared or ultraviolet beams of light. Owners of vehicles meeting the Clean Screen criteria are notified by the County Clerk that their vehicles have passed the motor vehicle inspection process and are exempt from their next regularly scheduled IM240 test.

The Clean Screen program component of Colorado's Reg. No. 11 was originally approved, for implementation in the Metro-Denver area, with the EPA's approval of the original Denver carbon monoxide (CO) redesignation to attainment and the maintenance plan (see: 66 FR 64751, December 14, 2001). The Clean Screen criteria that was approved in 2001 by the EPA (see: 66 FR 64751, December 14, 2001) required two valid passing remote sensing readings on different days or from different sensors, that met the applicable emissions reading requirements in Part F of Reg. No. 11, within a twelve-month period in order to clean-screen a vehicle.

Colorado revised Reg. No. 11 to expand the definition and requirements for a "clean-screened vehicle" to also include vehicles identified as low emitting vehicles in the state-determined Low Emitting Index (LEI) which have one passing remote sensing reading, prior to the vehicle's registration renewal date. As part of the LEI process, the Colorado Department of Public Health and Environment (CDPHE), Air Pollution Control Division (hereinafter, the "Division") develops an LEI on or before July 1st of each year. The LEI is based on a tabulation of the previous calendar year's IM240 inspection program results for specific make, model, and model year vehicles that passed IM240 vehicle inspections the previous year at a minimum rate of a 98%.

By a letter dated June 11, 2008, the Governor of Colorado submitted the above 2007 Reg. No. 11 LEI revisions and other minor revisions involving changes/additions to the definitions in Reg. No. 11and the addition of Attachment 1 to the Technical Specifications in Appendix A. These SIP revisions are discussed in further detail below in section IV.

b.) Colorado's 2012 Revisions to Regulation No. 11 for the Implementation of the On-Board Diagnostics Test Requirements Contained in Regulation No. 11 and the Seven Model Year I/M Test Exemption

As noted above, Colorado's Reg. No. 11 addresses the implementation of a motor vehicle I/M program that consists of a an "enhanced" component IM240 test for 1982 and newer light-duty vehicles and a TSI test for 1981 and older light-duty gas vehicles. In addition, and beginning in January 2015, Colorado also began implementing an On-Board Diagnostics (OBD) test for certain model year vehicles. An OBD I/M test essentially means the electronic retrieval, by connecting to the computer port data link connector (DLC) in the vehicle with an OBD test analyzer, of information from a vehicle's computer system. The electronic information retrieved addresses items such as stored readiness status, diagnostic trouble codes (DTC), malfunction indicator light (MIL) illumination and other data from a vehicle's OBD system. Electronically interrogating a vehicle's OBD system allows for the determination of whether any emission related DTCs are present and if the MIL is commanded on. Should these aspects of an OBD test be present, that would indicate the existence of an emissions related malfunction with the vehicle being tested.

In addition, Colorado also extended the Reg. No. 11 exemption from I/M testing for new vehicles from four years to seven years. This revision was based on Colorado's gathering of emissions testing information over a period of several years which demonstrated that historically new and newer vehicles typically did not fail the IM240 or OBD emissions test within the first seven years of the vehicle's life.

By a letter dated March 15, 2013, the Governor of Colorado submitted the above 2012 Reg. No. 11 OBD test requirements, the seven year test exemption, and other minor revisions. These SIP revisions are discussed in further detail below in section V.

c.) Colorado's 2013 Revisions to Regulation No. 11, Appendix A, Incorporation by Reference of Technical Materials, the Addition of New Technical Information/Requirements, and Minor Revisions to Appendix B

Colorado further revised Reg. No. 11 by updating Appendix A and Appendix B to remove text and incorporate by reference certain Attachments to Appendix A, to add new language to Appendix A, and to add new language and remove obsolete language in Appendix B.

Appendix A was revised to remove the text of three technical document attachments and to note that the documents are available at CDPHE's Emissions Technical Center Procedures Manual. The technical documents are incorporated by reference into Reg. No. 11. Appendix A. The technical documents that are incorporated by reference into Reg. No. 11 are: Attachment I "PDF 1000 Scanner," Attachment II "Thermal Transfer Printer," and Attachment III "Colorado Automobile Dealers Transient Mode Test Analyzer System." Appendix A was also revised by adding Attachment V "Specifications for Colorado On-Board Diagnostic (OBD) Stand-Alone Analyzer."

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[1] See 40 CFR part 51, subpart S for a complete description of EPA's IM240 test. The IM240 test is essentially an enhanced motor vehicle emissions test to measure mass tailpipe emissions while the vehicle follows a computer generated driving cycle trace for 240 seconds and while the vehicle is on a dynamometer.

[2] See 40 CFR part 51, subpart S for a complete description of EPA's two-speed idle test. The two-speed idle test essentially measures the mass tailpipe emissions of a stationary vehicle; one reading is at a normal idle of approximately 700 to 800 engine revolutions per minute (RPM) and one reading at 2,500 RPM.

Appendix B, which is entitled "Standards and Specifications for Calibration/Span Gas Suppliers," was revised with updated language in Section 1 "Definitions," Section 2 "Basic & Enhanced Idle Air Program/Technical Requirements," Section 3, "Calibration/Span Gas Approval & Labeling," Section 4 "Cylinder Tracking & Recall," Section 5 "Enhanced IM & IG 240 Air Program/Technical Requirements," Section 6 "Colorado Approval Process," and Section 7 "Blender Facility Requirements & Documentation." Obsolete language was also removed from Appendix B.

By a letter dated March 3, 2014, the Governor of Colorado submitted the above 2013 Reg. No. 11 revisions to Appendix A and Appendix B. These SIP revisions are discussed in further detail below in section VI.

III. What was the State's process?

Section 110(a)(2) of the CAA requires that a state provide reasonable notice and public hearing before adopting a SIP revision and submitting it to us.

a.) The State's June 11, 2008 SIP Submittal

On June 21, 2007 the Colorado Air Quality Control Commission (AQCC) conducted a public hearing to consider the adoption of revisions and additions to the Colorado SIP. The revisions affecting the SIP involved Reg. No. 11, the Clean Screen sections of Reg. No. 11, the LEI portion of the Clean Screen program, and associated revisions. After reviewing written comments, dated April 17, 2007, received from Rocky Mountain Clean Air Action and after conducting a public hearing, the AQCC adopted the proposed revisions to Reg. No. 11 on June 21, 2007. The SIP revisions became State effective on August 30, 2007.

We evaluated the State's June 11, 2008 submittal for Reg. No. 11 of the SIP and determined that the State met the requirements for reasonable notice and public hearing under section 110(a)(2) of the CAA. By a letter dated October 14, 2008, we advised James B. Martin, Executive Director of the CDPHE, that the SIP revisions submittal was deemed to have met the minimum "completeness" criteria found in 40 CFR part 51, Appendix V.

b.) The State's March 15, 2013 SIP Submittal

On December 20, 2012, the AQCC conducted a public hearing to consider the adoption of revisions and additions to the Colorado SIP. The revisions affecting the SIP involved Reg. No. 11, the OBD program, the seven model year exemption from I/M testing, and associated revisions. After reviewing one supportive email written comment, dated December 16, 2012, received from Bob Armott and after conducting a public hearing, the AQCC adopted the proposed revisions to Reg. No. 11 on December 20, 2012. The SIP revisions became State effective on February 15, 2013.

We evaluated the State's March 15, 2013 submittal for Reg. No. 11 of the SIP and determined that the State met the requirements for reasonable notice and public hearing under section 110(a)(2) of the CAA. By operation of law under section 110(k)(1)(B) of the CAA, the State's March 15, 2013 submittal was deemed complete on September 15, 2013.

c.) The State's March 3, 2014 SIP Submittal

On November 21, 2013, the AQCC conducted a public hearing to consider the adoption of revisions and additions to the Colorado SIP. The revisions affecting the SIP included updating Appendix A and Appendix B to Reg. No. 11 to remove text, incorporate by reference certain Attachments to Appendix A, to add new language to Appendix A, and to add new language and remove obsolete language in Appendix B. After conducting a public hearing, which did not have any public comments, the AQCC adopted the proposed revisions to Reg. No. 11 on November 21, 2013. The SIP revisions became State effective on December 30, 2013.

We evaluated the State's March 3, 2014 submittal for Reg. No. 11 of the SIP and determined that the State met the requirements for reasonable notice and public hearing under section 110(a)(2) of the CAA. By operation of law under section 110(k)(1)(B) of the CAA, the State's March 3, 2014 submittal was deemed complete on September 3, 2014.

IV. EPA's Evaluation of the State's 2007 Revisions to the Low Emitter Index, Part A, Part C, Part F, and Appendix A

a.) Evaluation of the Clean Screen Program and LEI Component

We approved the Clean Screen program component of Colorado's Reg. No. 11, for implementation in the Metro-Denver area with our approval of the original Denver carbon monoxide (CO) redesignation to attainment and the associated maintenance plan (see: 66 FR 64751, December 14, 2001). Additional discussion of the Clean Screen program was provided in our August 22, 2001 proposed rule (66 FR 44097). In evaluating the Clean Screen program for the maintenance plan, the State used EPA's MOBILE5b motor vehicle emissions calculation model and the MOBILE model's remote sensing program credit utility dated 1996[3] and revised in 1998.[4] Further discussion is also provided in the State's Technical Support Document (TSD) for the 2001 CO redesignation to attainment, which is part of the EPA's final rule hard copy docket, and is also available from the State on-line at: *http://www.colorado.gov/airquality/tech_doc_repository.aspx?action=open&file=codenfnl.pdf*).

For the Reg. No. 11 revisions that we approved on December 14, 2001, the State used the above tools and other data to evaluate the Clean Screen program for its implementation in the Metro-Denver area. Based on this evaluation and the review of information for the additional implementation of a Clean Screen program in Fort Collins (located in Larimer County, Colorado) and Greeley (located in Weld County, Colorado), the state concluded there would be an approximate 4% disbenefit for CO emissions and a 7% disbenefit for hydrocarbon (HC) emissions if it was assumed that 35% of the eligible vehicles were clean-screened.[5]

We note that the version of Reg. No. 11 that the EPA approved on December 14, 2001 included the Clean Screen criteria which required an eligible vehicle for inspection to have at least two consecutive passing remote sensing emissions readings performed on different days, or at different approved Clean Screen inspection sites, prior to its registration renewal date.

With the 2007 Reg. No. 11 revisions, the AQCC adopted modifications as proposed by the Division that expanded the Clean Screen criteria to also include vehicles with one passing remote sensing reading prior to its registration date and that the vehicle is identified as a low emitter on the LEI. To address the LEI criteria of this revised Clean Screen process, the Division develops a low emitting vehicle index on or before July 1st of each year based on a tabulation of the previous calendar year's IM240 inspection program results for specified make, model and model year vehicles. This LEI is comprised of specific make, model and model year vehicles that passed IM240 vehicle inspections the previous year at a minimum of a 98% rate. However, in developing the LEI, the Division may use passing criteria greater than 98% if necessary to ensure that the use of the LEI is equivalent or better than the use of a second remote sensing measurement in terms of air quality benefits. This process is more fully detailed in the CPDHE May, 2007 document entitled ''Development and Evaluation of Colorado's Low Emitter Index.''

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[3] "User Guide and Description For Interim Remote Sensing Program Utility," EPA/AA/AMD/EIG/96–01, dated September, 1996.

[4] "Program User Guide for Interim Vehicle Clean Screening Credit Utility," Draft Report, EPA420–P–98–007, dated May, 1998.

[5] "Revised Final Economic Impact Analysis for Inspection and Maintenance per C.R.S. 25–7–110.5(4)(I), Cost Effectiveness Economic Impact Analysis, 2/1/99."

To assess the State's Clean Screen program and its LEI component, the EPA reviewed the available CDPHE Clean Screen annual reports for 2009,[6] 2011,[7] 2012,[8] and 2013.[9] The annual reports detailed the overall effectiveness of the Clean Screen program and also contained the results of the random 2% sampling for the LEI component. This sampling procedure involved retaining 2% of the vehicles which had been shown to pass one measurement with RSD equipment and been on the LEI index, and then requiring them to take an IM240 test for comparison. The data, including fleet coverage and emissions reduction retention, are presented below in Tables 1 and 2:

TABLE 1—TOTAL VEHICLES INSPECTED AND VEHICLES CLEAN-SCREENED

Year of clean screen report	Total vehicles inspected	Vehicles that were clean-screened	Percent of total vehicles that were clean-screened (%)
2009	899,646	199,344	22.0
2011	1,156,949	246,768	21.3
2012	1,150,562	248,224	21.6
2013	1,184,875	233,760	19.7

TABLE 2—ESTIMATED CLEAN SCREEN DISBENEFIT—BASED ON RETAINED EMISSION REDUCTIONS

Year of clean screen report	Retained HC emission reductions (%)	Retained CO emission reductions (%)	Retained NO_X* emission reductions (%)
2009	94.6	98.1	92.9
2011	96.1	98.1	97.3
2012	94.8	97.1	93.9
2013	97.3	96.7	97.6
Average Clean Screen Disbenefit	4.3	2.5	4.6

* Nitrogen Oxides.

The data from the State's Clean Screen reports, as excerpted and presented in the above tables, demonstrate that the disbenefit from the Clean Screen program and its LEI component continue to be within the original estimates from the Reg. No. 11 revisions that we approved on December 14, 2001. Although those original 2001 disbenefit estimates (4% for CO, 7% for HC, and assuming 35% clean-screened vehicles) were prepared with then current tools, the Clean Screen program and LEI component continue to perform within those estimates. Also, from the above four years of Clean Screen annual reports that we evaluated, the State's Reg. No. 11 revisions original estimate of 35% of the fleet being clean-screened has not been achieved. Based on the four referenced Clean Screen reports, we note that 22% or less of the eligible vehicles have been clean-screened. Therefore, the actual emission reduction disbenefit has been less than predicted, as more vehicles have then been required to go through the IM240 test.

b.) The Sections of Reg. No. 11 That Were Revised With the State's June 11, 2008 Submittal Were as Follows:

1.) *Part A, section II:* Modify definition number 15 ''Clean Screened Vehicle'' to reflect the addition of the LEI; modify definition number 17 ''Colorado '4'' to clarify the use of the BAR 90 test analyzer systems for use after 1994; and add a new definition ''Low Emitting Vehicle Index.'' Renumber definitions number 18 and higher.

2.) *Part C, section XII:* Modify section XIIA.3 regarding the requirements and procedures to clean screen an eligible vehicle and add section XIIE.4 regarding low emitting vehicles and the LEI.

3.) *Part F, section VI:* Renumber section VI.B as VI.C; add new section VI.B.1 which requires the development of the LEI each year; add new section VI.B.2 which establishes the 98% minimum passing criteria for the LEI; and add new section VI.B.3 which allows the Division to use a greater than 98% passing criteria if needed to equate to a second RSD reading.

4.) *Appendix A, Technical Specifications, Attachment 1:* Sections of Attachment 1 of the Technical Specifications contain the specifications for the PDF 1000 Scanner; some sections were unreadable and a full, retyped PDF 1000 Scanner section was provided.

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[6] ''The Colorado Remote Sensing Program January–December, 2009,'' Colorado Department of Public Health and Environment, July, 2010.

[7] ''The Colorado Remote Sensing Program January–December, 2011,'' Colorado Department of Public Health and Environment, November, 2012.

[8] ''The Colorado Remote Sensing Program January–December, 2012,'' Colorado Department of Public Health and Environment, December, 2013.

[9] ''The Colorado Remote Sensing Program January–December, 2013,'' Colorado Department of Public Health and Environment, September, 2014.

5.) *Appendix A, Technical Specifications, Attachment 2:* Sections of Attachment 2 of the Technical Specifications contain the specifications for the Thermal Transfer Printer; some sections were unreadable and a full, retyped Thermal Transfer Printer section was provided.

The EPA notes that Part F, section III.A.2 of Reg. No. 11 was also provided with the State's June 11, 2008 submittal. This section contains IM240 test light duty vehicle emissions cutpoints for 1996 and newer vehicles (all in grams per mile). The CO, HC, and NO_X entries for calendar year 2006 are incorrect as the State had previously provided an August 8, 2006 SIP revision submittal to remove these 2006 cutpoints (*i.e.,* HC 0.6, CO 10.0, and NO_X 1.5). The EPA approved the removal of these 2006 cutpoints on December 20, 2012 (77 FR 75388).

V. EPA's Evaluation of the State's 2012 Revisions to the On-Board Diagnostics Test, the Seven Model Year Emissions Test Exemption, the Gas Cap Retest, Part A, Part B, Part C, Part F, and Part G

a.) Evaluation of the OBD Test Provisions

As we noted above, beginning in January 2015, Colorado began implementing an OBD test for certain model year vehicles. An OBD I/M test essentially means the electronic retrieval, by connecting to the computer port DLC in the vehicle with an OBD test analyzer, of information from a vehicle's computer system addressing items such as stored readiness status, DTCs, MIL illumination and other information from a vehicle's OBD system. Electronically interrogating a vehicle's OBD system allows for the determination if any emission related DTCs are present and if the MIL is commanded on. Should these aspects of an OBD test be present, that would indicate the existence of an emissions related malfunction with the vehicle being tested. More detailed information on OBD I/M testing is found in 40 CFR 85, Subpart W and at the EPA's Office of Transportation and Air Quality (OTAQ) Web site at: *http://www3.epa.gov/obd/regtech/inspection.htm.* In addition, further information is provided in the EPA's OBD rulemaking actions of April 5, 2001 (66 FR 18156), December 20, 2005 (70 FR 75403), and the EPA's document addressing performing OBD system checks as part of an I/M program.[10]

The EPA has reviewed the OBD information in the State's Administrative documentation with its March 15, 2013 submittal, the OBD I/M test procedures contained in the Reg. No. 11 revisions to Part A, Part B, Part C, and Part F, all as detailed further below, and has concluded these revisions meet the requirements of 40 CFR 85, Subpart W for OBD I/M testing and the above cited EPA final rules.

We note the Colorado OBD test provisions that were adopted in 2012 are applicable to a portion of the vehicles that are subject to an I/M test. The Reg. No. 11 revisions of 2012 also increased the new vehicle model year exemption from four to seven years, required OBD testing for the next four years (two inspection cycles for the 8th through 11th years), and required I/M 240 testing to commence with the third inspection cycle. In addition, the Reg. No. 11 revisions of 2012 allowed OBD testing for OBD equipped vehicles that were otherwise hard to test with the IM240 procedures (for example, too short of a wheelbase for the dynamometer treadmills, vehicles with very large or small wheel/tire combinations, and certain all-wheel-drive vehicles with very sensitive traction control systems), eliminated the visual inspection for 1996 and newer vehicles (because of OBD testing), and required a full emissions retest for vehicles initially failing the gas cap test. The 2012 Reg. No. 11 revisions retained other aspects of the I/M program including the use of Clean Screen technology to clean screen vehicles and annual TSI testing for 1981 and older vehicles.

In consideration of the OBD testing component of the I/M program and the extension from four years to seven years to exempt new vehicles from I/M testing (discussed further below), the State prepared an estimated emissions benefit for the implementation of both the OBD testing and extended test exemption for seven years. This estimated emissions benefit information is contained in the Administrative Documentation, that is part of the State's March 15, 2013 SIP submittal, and is provided in the section entitled "SIP Emission Reduction Equivalency Demonstration." The information notes that the Division conducted modeling of the 2012 revisions using the then current I/M program, as implemented in the seven Metro-Denver counties area, and the new program (OBD plus the seven-year testing exemption) as fully implemented in 2017. The year 2017 was selected as that would reflect the full completion of a two-year OBD inspection cycle on applicable vehicles. The Division's results are provided below in Table 3:

TABLE 3—SEVEN COUNTY METRO-DENVER AREA I/M PROGRAM ESTIMATED REDUCTIONS IN 2017

	TGH *	NO_X	CO
Current I/M Program	6.008 tpd **	4.849 tpd	68.843 tpd.
Revised I/M Program	6.052	5.004	64.916.

*Total Gaseous Hydrocarbons.
**tons per day (tpd).

As shown in Table 3 above, implementation of the Reg. No. 11 provisions of the OBD component and the seven-year exemption from I/M testing were estimated to result in a small increase in CO emissions and a slight reduction in ozone precursor emissions (NO_X and TGH).

The EPA has evaluated this negligible increase in estimated CO emissions and has concluded it will not have a detrimental effect on the most recently-approved revised Metro-Denver CO maintenance plan (72 FR 46148, August 17, 2007).[11] Our evaluation considered the negligible increase in CO emissions of four tpd to the CO mobile sources emission inventory data in the Metro-

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[10] "Performing Onboard Diagnostic System Checks as Part of a Vehicle Inspection and Maintenance Program," EPA–420–R–01–015, dated June, 2001.

[11] "Approval and Promulgation of Air Quality Implementation Plans; State of Colorado; Revised Denver and Longmont Carbon Monoxide Maintenance Plans, and Approval of Related Revisions," 72 FR 46148, dated August 17, 2007.

Denver maintenance plan for the projected 2015 mobile source CO emissions of 1,416 tpd and the maintenance plan's final maintenance year of 2021 projected mobile source CO emissions of 1,372.10 tpd. The four tpd emissions would be 0.28% of the 2015 CO mobile source emissions and 0.29% of the 2021 CO mobile source emissions. In addition, we also reviewed state-certified and EPA-reviewed ambient CO air quality monitoring data that are located in the EPA's Air Quality System (AQS) database. We reviewed data from 2007 through 2015. We did not find any exceedances or violations of the CO National Ambient Air Quality Standards (NAAQS). Therefore, the Metro-Denver CO maintenance area continues to demonstrate maintenance of the CO NAAQS.

We do note that the slight reduction in ozone precursor emissions of NO_X and TGH will be beneficial as the Metro-Denver/North Front Range (NFR) 2008 8-hour ozone NAAQS nonattainment area continues to work towards attainment of that NAAQS. Additional information regarding the Metro Denver/NFR ozone nonattainment area and its status can be found in the EPA's 2008 ozone NAAQS proposed SIP Requirements rule (80 FR 51992, August 27, 2015)[12] and final rule (81 FR 26697, May 4, 2016).[13]

b.) Evaluation of the Extension of the I/M Test Exemption From Four to Seven Years

Included with the March 15, 2013 Reg. No. 11 SIP revision submittal were revised provisions to increase the I/M test exemption for newer vehicles from the EPA-approved four-year exemption to seven years. Additional information and rationale were provided by the Division in the "Air Quality Control Commission Regulation Number 11 Motor Vehicle Emissions Detailed Issue Statement" which was part of the SIP submittal's Administrative Documentation.

The Division's AQCC issue statement noted that the revision to Reg. No. 11, to increase new vehicle model year exemptions from four years to seven years, was allowed by Colorado law which authorizes the AQCC to extend the duration for which new vehicles are exempt from I/M testing; 42–4–310(1)(a)(II)(C) and 42–4–306(8)(b), Colorado Revised Statute (C.R.S.)

The Division noted that the revision to extend the new vehicle model year exemption results in an overall cost savings and increased convenience to the public for tests not performed. In addition, the Division stated that the population of vehicles in this age group, and their vehicle miles traveled, are relatively high; however, since they are relatively new vehicles, their emissions are lower than those of older vehicles.

The Division concluded that increasing the duration of the new vehicle exemption increases emissions from the entire fleet. However, the EPA notes that with this particular revision to Reg. No. 11, the State simultaneously included revisions to Reg. No. 11 to initiate OBD testing requirements for applicable vehicles. As discussed above and as presented in Table 3 above, the net result of the implementation of both the seven-year extended exemption for I/M test and OBD testing showed a negligible increase of CO emissions and a slight decrease in NO_X and TGH emissions. Based on our above analysis of the Metro-Denver CO maintenance plan and relevant ambient CO air quality monitoring data, the EPA finds that the increase in the new vehicle seven-year I/M test exemption will not have an adverse effect on the approved revised Metro-Denver CO maintenance plan (72 FR 46148, August 17, 2007). We also find that the emissions from the revised seven-year I/M test exemption are offset by the additional reduction in ozone precursor emissions of NO_X and TGH realized through the State's implementation of OBD testing that covers the Metro-Denver/NFR 2008 8-hour ozone NAAQS nonattainment area.

c.) Gas Cap Full Retest Clarification and Other Minor Non-Substantive Revisions

There was a clarification to the gas cap test requirements and several other minor revisions included with the March 15, 2013 Reg. No. 11 SIP revision submittal.

The state revised Reg. No. 11 to clarify that, in accordance with federal law, a full I/M retest is required after a test failure due to the lack of a gas cap or a faulty gas cap. The EPA notes that missing or malfunctioning gas caps automatically cause a test failure and require replacement of the cap and then a full emissions retest. The full retest is necessary because the gas cap seals and pressurizes the entire fuel evaporative emissions control system. If other components of the evaporative system are functional, there will be no effect on tailpipe emissions; however, if other elements of the evaporative system are faulty replacing a faulty or missing gas cap can trigger a tailpipe emissions failure. In addition, the inclusion or replacement of a malfunctioning gas cap will reduce emissions of volatile organic compounds (VOC) from a vehicle's fuel tank. This is a beneficial as VOCs are a precursor emission to the formation of ground level ozone.

The Reg. No. 11 revisions also include several 'housekeeping' items including: Correcting typographical and grammatical errors; deleting obsolete language and implementation dates; removing titles and text that were inadvertently left unchanged from prior Reg. No. 11 changes; and renumbering and recodifications according to adopted language additions and deletions.

d.) The Sections of Reg. No. 11 That Were Revised With the State's March 15, 2013 Submittal Were as Follows:

1.) *Part A, section I:* Minor wording changes to add new language and remove obsolete language in sections I.B, I.C.3, I.C.3.a, I.C.3.b, I.C.3.c, I.C.4, I.C.7, I.C.7.c, I.C.8, and I.C.9.b.

Part A, section II: A new definition number 20 was added entitled "Colorado On-Board Diagnostic (OBD) Test Analyzer System;" a new definition number 22 was added entitled "Diagnostic Trouble Code (DTC);" and, definitions number 23 to 43 were renumbered. A new definition number 44 was added and entitled "On-Board Diagnostics II (OBD or OBDII) Test" and definitions numbered 45 to 52 were renumbered.

Part A, section IV: Section IV. D was removed which involved obsolete language and section IV.E was renumbered IV.D and also had obsolete language removed.

2.) *Part B, section IX:* Section IX was added and is entitled "Approval of the Colorado On-Board Diagnostic (OBD) Test Analyzer System. Also, Part B, section X was added and is entitled "The Colorado On-Board Diagnostic (OBD) Test Analyzer System."

3.) *Part C, title:* The title was modified by adding "On-Board Diagnostics (OBD)."

Part C, section I.C.3: This involved minor language changes to clarify data transmission and analyzer requirements.

Part C, section II.A: This section was renumbered from II.A through II.F to instead become II.A.1 through II.A.11. Minor clarification language was added along with revised references to sections in Part C.

Part C, section II.G: This section was renumbered to II.B and clarifying language was added regarding OBD testing. Sections II.G.1 through II.G.6 were renumbered II.B.1 through II.B.6. Section II.B.4 had clarifying language added regarding applicable vehicles that were unable to be tested with the IM240 test would then be OBD tested.

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[12] "Determinations of Attainment by the Attainment Date, Extensions of the Attainment Date, and Reclassification of Several Areas Classified as Marginal for the 2008 Ozone National Ambient Air Quality Standards," 80 FR 51992, dated August 27, 2015.

[13] "Determinations of Attainment by the Attainment Date, Extensions of the Attainment Date, and Reclassification of Several Areas Classified as Marginal for the 2008 Ozone National Ambient Air Quality Standards," 81 FR 26697, dated May 4, 2016.

Part C, section II.C: A new section II.C (II.C 1 through II.C.9) was added which specifies which vehicles are to be OBD tested and the requirements and testing procedures for an OBD test.

Part C, section III.A: This section had clarifying language added and sections III.B and III.C were removed as they addressed the model year 1996 and newer visual inspection procedures. The remaining applicable portions of section III.C were then renumbered III.B. Sections III.D and III.E were renumbered to III.C and III.D.

Part C, section IV: A new section IV was added which addressed the requirements for applicable vehicles (1996 through those vehicles that had reached their 11th model year of age) to be evaluated with and OBD test.

Part C, prior section IV: The existing section IV was renumbered section V and also modified with clarifying language regarding the requirement for a full retest of vehicles which previously had a missing or malfunctioning gas cap.

Part C, section VIII.A.2: A new section VIII.A.2 was added which states that vehicles in their model years seven through 10 need to meet the OBD passing criteria in Part F, section VII. Sections VIII.A.2 through VIII.A.4 were renumbered VIII.A.3 through VIII.A.5.

Part C, sections VIII.B.1, VIII.B.2, and VIII.B.3: These sections had minor wording changes and deletion of obsolete language.

Part C, sections VIII.D.A through VIII.D.E: These sections were renumbered VIII.D.1 through VIII.D.5.

Part C, sections IX.G and X.A: These sections had minor clarifying language added.

4.) *Part F, section V:* This section was entitled "Visible Smoke."

Part F, section VII: A new section VII was added (sections VII.A through VII.F) which stated the required OBD diagnostic inspection test passing criteria.

5.) *Part G:* This part had previously contained obsolete high-emitting vehicle identification pilot project language which was removed and Part G was retitled "Reserved."

VI. EPA's Evaluation of the State's 2013 Revisions to Part A, Part C, Appendix A, and Appendix B

In 2013, the AQCC adopted several minor changes to Reg. No. 11. These revisions were subsequently submitted to the EPA on March 3, 2014. The sections of Reg. No. 11 that were revised with the State's March 3, 2014 submittal were as follows:

a.) *Part A, section I.C.3.c:* This section was revised to clarify that the seven year new vehicle exemption, which excused vehicles from an I/M test for seven years and was previously adopted by the AQCC in December 2012, would take effect on January 1, 2015. Also, this exemption would apply retroactively to existing vehicles in their fourth, fifth, and sixth years of service.

b.) *Part A, sections I.C.8, I.C.9, and I.C.10:* These sections were revised to clarify ambiguous, contradictory and obsolete Reg. No. 11 language concerning the issuance of and duration periods for "Verification of Emissions Test" exemption windshield stickers issued by motor vehicle dealers. Part A, section I.C.8 was further clarified to note that vehicles in their fourth, fifth, and sixth years of service would have the seven year exemption applied retroactively.

c.) *Part A, section I.C.3 and Part C, sections III and IV:* These sections were revised to clarify that the seven-year new vehicle exemption from I/M testing, OBD testing requirements and procedures, and other changes made to Reg. No. 11 by the AQCC in December 2012, would go into effect January 1, 2015. In addition, the I/M visual inspection procedures for 1996 and newer vehicles would be retained through December 2014.

d.) *Part C, section C VIII.B.3:* This section was revised to codify in Reg. No. 11 the vehicle emissions repair cost waiver amount of $715. The AQCC has previously directed the Division to change the amount from $450 to $715 in November 2002, which was done. However, at that time, the AQCC had declined to note the changed repair amount in the text of Reg. No. 11.

e.) *Part C, section VIII.D.4:* This section was revised regarding the qualifying criteria for an economic hardship waiver for a vehicle failing its emissions test. Section VIII.D.4 was further revised to allow the economic hardship waiver to apply to households owning two vehicles rather than restricting hardship waivers to households owning only one vehicle.

f.) *Appendix A of Reg. No. 11 was revised as follows:*

1.) Appendix A was revised to remove the text of three technical document attachments and to note that the documents are available at CDPHE's Emissions Technical Center Procedures Manual. The technical documents are incorporated by reference into Reg. No. 11. Appendix A. The technical documents that are incorporated by reference into Reg. No. 11 are: Attachment I "PDF 1000 Scanner," Attachment II "Thermal Transfer Printer," and Attachment III "Colorado Automobile Dealers Transient Mode Test Analyzer System."

2.) Updated Attachment IV, entitled "Colorado Department of Public Health and Environment Specification for Colorado 97 Analyzer," to reflect technological changes to data specifications, communications protocols, and forms generation.

3.) Included a new Attachment V *"Test Analyzer Specification for On-board Diagnostics"* for licensed fleets who self-inspect their own vehicles. Note: Part B section X required this Test Analyzer Specification to be in place by December 31, 2013.

g.) *Appendix B of Reg. No. 11 was revised as follows:*

1.) Attachment II; the "Calibration Span Gas" labels were updated to reflect the current version of the State-official labels.

h.) Overall revised formatting and other non-substantive changes were made throughout Reg. No. 11.

VII. Conclusion

Our review of the State's Reg. No. 11 revisions, as presented above in sections IV, V, and VI, involved: 1.) The Low Emitter Index (LEI) and Clean Screen program components, 2.) The On-Board Diagnostics (OBD) I/M testing program component, 3.) The seven model-year exemption from I/M testing provisions, 4.) The requirement for a full I/M retest after the replacement of a missing or malfunctioning gas cap, 5.) New definitions, clarification language, and removal of obsolete language, 6.) Numerous revisions to Reg. No. 11 Parts A, B, C, F, G, Appendix A, and Appendix B, and 7.) Overall formatting, correction of typographic errors and other non-substantive changes. Based on our review and evaluation discussion presented above, we have determined that the Reg. No. 11 SIP revisions, submitted by the State in letters dated June 11, 2008, March 15, 2013 and March 3, 2014 sufficiently address applicable provisions in 40 CFR 51, Subpart S, 40 CFR 85, Subpart W, and applicable EPA guidance for I/M programs and that our approval is warranted.

VIII. Consideration of Section 110(l) of the Clean Air Act

Section 110(l) of the CAA states that a SIP revision cannot be approved if the revision would interfere with any applicable requirement concerning attainment and reasonable further progress towards attainment of a NAAQS or any other applicable requirement of the CAA. The only portions of the Reg. No. 11 revisions that we described above which we believe require further consideration with regard to section 110(l) of the CAA are the revisions to the Clean Screen program to add the LEI component and the seven-year I/M test exemption.

For the LEI component of the Clean Screen program, we noted above that with our December 14, 2001 approval the Metro-Denver CO maintenance plan and implementation of the Clean Screen program as adopted at that time, the State concluded there would be an approximate 4% disbenefit for CO emissions and a 7% disbenefit for HC emissions if it was assumed that 35% of the eligible vehicles were clean-screened. Our further evaluation of the LEI component of the Clean Screen program, as discussed above in section IV, involved the review of the State's Clean Screen annual reports for 2009, 2011, 2012 and 2013. The annual reports detailed the overall effectiveness of the Clean Screen program and also contained the results of the random 2% sampling for the LEI component. The data from the State's Clean Screen reports demonstrate that the disbenefit from the Clean Screen program, including its LEI component, continue to be within the original estimates from the Reg. No. 11 revisions that we approved on December 14, 2001. Although those original 2001 disbenefit estimates (4% for CO, 7% for HC, and 35% vehicles being clean-screened) were prepared with then current tools, the Clean Screen program and LEI component continue to perform within those estimates. Also, from the above four years of Clean Screen annual reports that we evaluated, the State's Reg. No. 11 revisions original estimate of 35% of the fleet being clean-screened has not be been achieved. Based on the four referenced Clean Screen reports, we note that 22% or less of the eligible vehicles have been clean-screened. Therefore, the actual emissions reduction disbenefit has been less than predicted as more vehicles have then been required to go through the IM240 test.

With regard to the seven-year new vehicle exemption from I/M testing, as explained above in section V, we noted that with the implementation of the Reg. No. 11 provisions of the combination of the OBD testing component and the seven-year exemption from I/M testing there was estimated to be a small increase in CO emissions and a minor reduction in ozone precursor emissions (NO_X and TGH). As noted above, the EPA evaluated this small increase in estimated CO emissions and has concluded it will not have a detrimental effect on the approved revised Metro-Denver CO maintenance plan (72 FR 46148, August 17, 2007). Our evaluation considered the negligible increase in CO emissions of approximately four tons per day as compared to the CO mobile sources emission inventory data in the Metro-Denver CO maintenance plan. As we noted above, the maintenance plan's estimated 2015 mobile source CO emissions are 1,416 tpd and the estimated 2021 (last year of the maintenance plan) mobile source CO emissions are 1,372.10 tpd. Therefore, the four tpd increase would be 0.28% of the 2015 mobile source CO emissions and the 0.29% of the 2021 mobile source CO emissions. We also reviewed available state-certified and EPA-reviewed ambient CO air quality monitoring data from the EPA's AQS database from 2007 through 2015. These data show no exceedance or violation of the CO NAAQS. We further noted that the minor increase in reductions of ozone precursor emissions of NO_X and TGH will be beneficial as the Metro-Denver/NFR 2008 8-hour ozone NAAQS nonattainment area continues to work towards attainment of that NAAQS.

With respect to other NAAQS that have the potential to be affected by our proposed approval of the above Reg. No. 11 revisions, we note that the Metro-Denver area is designated "unclassifiable/attainment" for the 1-hour NO_2 NAAQS[14] and the annual and 24-hour $PM_{2.5}$ NAAQS[15] (see: 40 CFR 81.306). We reviewed available state-certified and EPA-reviewed ambient air quality monitoring data for the 1-hour NO_2 NAAQS, and the annual and 24-hour $PM_{2.5}$ NAAQS. Our review involved EPA's AQS database and relevant data from 2007 through 2015. The data demonstrate continued attainment of the 1-hour NO_2 and $PM_{2.5}$ annual and 24-hour NAAQS in the Metro-Denver area.

In addition to the above, we have determined the revisions to Reg. No. 11 contained in all three SIP revision submittals involving the language changes necessary to implement the LEI and Clean Screen program components, the OBD I/M testing program component, the seven model-year exemption from I/M testing provisions, the requirement for a full I/M retest after the replacement of a missing or malfunctioning gas cap, new definitions, clarification language, removal of obsolete language, numerous minor revisions to Parts A, B, C, F, G, Appendix A and Appendix B of Reg. No. 11, overall formatting, correction of typographic errors and other non-substantive changes do not affect emissions and therefore do not have CAA section 110(l) implications.

In view of the above, the EPA proposes to find that the revisions to Colorado's Reg. No. 11 that are contained in the State's SIP submittals dated June 11, 2008, March 15, 2013 and March 3, 2014 will not interfere with attainment, reasonable further progress, or any other applicable requirement of the CAA.

IX. Proposed Action

The EPA is proposing approval of the June 11, 2008 submitted SIP revisions to Colorado's Regulation Number 11, Part A, Part C, Part F, and Appendix A. The EPA notes that Part F, section III.A.2 was also provided with the State's June 11, 2008 submittal. This section contains IM240 test light duty vehicle emissions cutpoints for 1996 and newer vehicles (all in grams per mile). The CO, HC, and NO_X entries for calendar year 2006 are incorrect as the State had previously provided an August 8, 2006 SIP revision submittal to remove these 2006 cutpoints (*i.e.*, HC 0.6, CO 10.0, and NO_X 1.5). EPA approved the removal of these 2006 cutpoints on December 20, 2012 (77 FR 75388).

In addition, the EPA is proposing approval of the March 15, 2013 submitted SIP revisions to Regulation Number 11, Part A, Part B, Part C, Part F, and Part G. Finally, the EPA is proposing approval of the March 3, 2014 submitted SIP revisions to Regulation Number 11, Part A, Part C, Appendix A, and Appendix B.

X. Incorporation by Reference

In this rule, the EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference Colorado Air Quality Control Commission, Regulation Number 11 as discussed in section IX of this preamble. The EPA has made, and will continue to make, these documents generally available electronically through *www.regulations.gov* and/or at the EPA Region 8 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

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[14] 1-hour NO_2 NAAQS: 75 FR 6474, February 9, 2010.

[15] $PM_{2.5}$ NAAQS: Annual NAAQS (78 FR 3086, January 15, 2013); 2006 24-hour NAAQS (71 FR 61144, October 17, 2006).

XI. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations [42 U.S.C. 7410(k), 40 CFR 52.02(a)]. Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this proposed action merely approves some state law as meeting federal requirements and disapproves other state law because it does not meet federal requirements; this proposed action does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, Oct. 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, Aug. 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and,
- Does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, Feb. 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian Country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, and Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: July 26, 2016.

Shaun L. McGrath,

Regional Administrator, Region 8.

[FR Doc. 2016–18878 Filed 8–11–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2015–0724; FRL–9950–51–Region 5]

Air Plan Approval; Indiana; Abengoa Bioenergy of Indiana, Commissioner's Order

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a revision to the Indiana State Implementation Plan (SIP) submitted by the Indiana Department of Environmental Management (IDEM) on October 16, 2015. The submittal consists of an order issued by the Commissioner of IDEM (Commissioner's Order No. 2015–01) approving alternative control technology requirements for Abengoa Bioenergy of Indiana (Abengoa). These requirements include the use of a carbon adsorption/absorption hydrocarbon vapor recovery system with a minimum overall control efficiency of 98% to control volatile organic compound (VOC) emissions from the ethanol loading racks at Abengoa. A continuous emissions monitoring system (CEMS) must be used to monitor the carbon adsorption/absorption hydrocarbon vapor recovery system for breakthrough of VOC emissions.

DATES: Comments must be received on or before September 12, 2016.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2015–0724, at *http://www.regulations.gov* or via email to *aburano.douglas@epa.gov.* For comments submitted at *Regulations.gov,* follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Jenny Liljegren, Physical Scientist, Attainment Planning and Maintenance Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–6832, *Liljegren.Jennifer@epa.gov.*

SUPPLEMENTARY INFORMATION: In the Final Rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this rule, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. For additional information, see the direct final rule which is located in the Rules section of this **Federal Register**.

Dated: August 1, 2016.

Robert A. Kaplan,

Acting Regional Administrator, Region 5.

[FR Doc. 2016–19030 Filed 8–11–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2014–0008; FRL–9949–53]

Receipt of Several Pesticide Petitions Filed for Residues of Pesticide Chemicals in or on Various Commodities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing of petitions and request for comment.

SUMMARY: This document announces the Agency's receipt of several initial filings of pesticide petitions requesting the establishment or modification of regulations for residues of pesticide chemicals in or on various commodities.

DATES: Comments must be received on or before September 12, 2016.

ADDRESSES: Submit your comments, identified by docket identification (ID) number and the pesticide petition number (PP) of interest as shown in the body of this document, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT** for the division listed at the end of the pesticide petition summary of interest.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

II. What action is the agency taking?

EPA is announcing its receipt of several pesticide petitions filed under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, requesting the establishment or modification of regulations in 40 CFR part 180 for residues of pesticide chemicals in or on various food commodities. The Agency is taking public comment on the requests before responding to the petitioners. EPA is not proposing any particular action at this time. EPA has determined that the pesticide petitions described in this document contain the data or information prescribed in FFDCA section 408(d)(2), 21 U.S.C. 346a(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the pesticide petitions. After considering the public comments, EPA intends to evaluate whether and what action may be warranted. Additional data may be needed before EPA can make a final determination on these pesticide petitions.

Pursuant to 40 CFR 180.7(f), a summary of each of the petitions that are the subject of this document, prepared by the petitioner, is included in a docket EPA has created for each rulemaking. The docket for each of the petitions is available at *http://www.regulations.gov.*

As specified in FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), EPA is publishing notice of the petition so that the public has an opportunity to comment on this request for the establishment or modification of regulations for residues of pesticides in or on food commodities. Further information on the petition may be obtained through the petition summary referenced in this unit.

1. *PP 6F8443.* (EPA–HQ–OPP–2015–0561). ISK Biosciences Corporation, 7470 Auburn Road, Suite A, Concord, Ohio, 44077, requests to establish a tolerance for residues of the combined residues of the insecticide flonicamid [N-(cyanomethyl)-4-trifluoromethyl)-3-pyridinecarboxamide (CA) or N-cyanomethyl-4-

trifluoromethylnicotinamide (IUPAC)] and its metabolites, TFNA [4-trifluoromethylnicotinic acid], TFNA–AM [4-trifluoromethylnicotinamide) and TFNG [N(4-trifluoromethylnicotinoyl)-glycine] in or on the raw agricultural commodity crop group 10–10, citrus at 1.5 parts per million (ppm). Adequate enforcement methodology is available to enforce the tolerance expression for flonicamid and its metabolites in/on appropriate raw agricultural commodities and processed commodities are available for the established and proposed tolerances. *Contact:* Carmen Rodia, (703) 306–0327, *rodia.carmen@epa.gov.*

2. *PP 6E8466.* (EPA–HQ–OPP–2016–0029). Gowan Company, P.O. Box 5569, Yuma, AZ 85366–5569, requests to establish an import tolerance for residues of fenazaquin, [3-[2-[4-(1, 1-dimethylethyl) phenyl] ethoxy] quinazoline] in/on the raw agricultural commodity for tea at 9 ppm and pineapple at 0.2 ppm. The analytical method for the analysis of fenazaquin in/on tea was conducted by GC–MS in selected ion monitoring mode. The analytical method used for the determination of fenazaquin in or on pineapple was conducted by UPLC employing mass spectrometric detection (LC–MS/MS). *Contact:* Carmen Rodia, (703) 306–0327, *rodia.carmen@epa.gov.*

3. *PP 6F8468.* (EPA–HQ–OPP–2016–0416). BASF Corporation, 26 Davis Drive, P.O. Box 13528, Research Triangle Park, NC 27709–3528, requests to establish a tolerance for residues of the insecticide afidopyropen, [(3*S*,4*R*,4a*R*,6*S*, 6aS, 12*R*,12a*S*,12b*S*)-3-(cyclopropanecarbonyloxy)-6,12-dihydroxy-4,6a,12b-trimethyl-11-oxo-9-(pyridin-3-yl)-1,2,3,4,4a,5,6,6a,12a,12b-decahydro-11*H*,12*H*-benzo[*f*]pyrano[4,3-*b*]chromen-4-yl]methyl cyclopropanecarboxylate, its metabolites, and degradates, in or on the raw agricultural commodities almond hulls at 0.15 ppm; apple, wet pomace at 0.05 ppm; citrus oil at 0.3 ppm; cotton, gin byproducts at 2 ppm; cotton, undelinted seed at 0.1 ppm; fruit, citrus, group 10–10 at 0.15 ppm; fruit, pome, group 11–10 at 0.03 ppm; fruit, stone, group 12–12 at 0.03 ppm; nut, tree, group 14–12 at 0.01 ppm; plum, prune at 0.06 ppm; soybean, aspirated fractions at 0.4 ppm; soybean, forage at label restriction ppm; soybean, hay at label restriction ppm; soybean, seed at 0.01 ppm; vegetable, brassica, head and stem group 5–13 at 0.5 ppm; vegetable, cucurbit, group 9 at 0.7 ppm; vegetable, fruiting, group 8–10 at 0.15 ppm; vegetable, leaf petioles, subgroup 22B at 3 ppm; vegetable, leafy, subgroup 4–13A at 2 ppm; vegetable leafy, subgroup 4–13B at 5 ppm; and vegetable tuberous and corm, subgroup 1C at 0.01 ppm.

An independently validated analytical method has been submitted for analyzing residues of parent afidopyropen (BAS 440 I) plus metabolite M440I007 with appropriate sensitivity in all crop and processed commodities. An independently validated analytical method has been submitted for analyzing residues of parent afidopyropen (BAS 440 I) plus metabolite M440I001, M440I003, and M440I060 in animal meat, fat and liver and egg and for BAS 440 I and metabolites M440I001, M440I005, and M440I060 in milk with appropriate sensitivity in the event tolerances are established. A multi-residue method using modified AOAC Official method 2007.01 for the determination of residues of afidopyropen (BAS 440 I) and metabolite M440I007 in plant matrices was successfully validated. *Contact:* Carmen Rodia, (703) 306–0327, *rodia.carmen@epa.gov.*

4. *PP 6E8463.* (EPA–HQ–OPP–2007–0099). Nichino America, Inc., 4550 New Linden Hill Road, Suite 501, Wilmington, DE 19808–2951, requests to establish an import tolerance for residues of flubendiamide, N^2-[1,1-dimethyl-2-(methylsulfonyl)ethyl-3-iodo-N^1-[2-methyl-4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]phenyl]-1,2-benzenedicarboxamide, in/on the processed commodity dried tea at 60 ppm. Independently validated, analytical methods for crop matrices have been submitted for measuring flubendiamide. Typically, plant matrices samples are extracted, concentrated, and quantified by LC/MS/MS using deuterated internal standards. *Contact:* Carmen Rodia, (703) 306–0327, *rodia.carmen@epa.gov.*

Authority: 21 U.S.C. 346a.

Dated: August 5, 2016.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2016–19239 Filed 8–11–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–2000–0006; FRL–9950–61–Region 2]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Deletion of the Jackson Steel Superfund Site

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; notice of intent for deletion.

SUMMARY: The Environmental Protection Agency (EPA), Region 2, is issuing this Notice of Intent to Delete (NOID) the Jackson Steel Site, located in the Village of Mineola, Nassau County, New York, from the National Priorities List (NPL) and requests public comments on this proposed action. The NPL, promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan. EPA and the State of New York, through the New York State Department of Environmental Conservation (NYSDEC), have determined that other than the ongoing operation and maintenance of the vapor intrusion mitigation systems at the daycare center, periodic vapor intrusion monitoring, ensuring that the institutional controls are in place and effective, and five-year reviews, all appropriate response actions under CERCLA have been completed at the Site and that the soil on the Site and the groundwater beneath the Site no longer pose a threat to public health or the environment.

DATES: Comments must be received by *September 12, 2016.*

ADDRESSES: Submit your comments, identified by Docket ID no. EPA–HQ–SFUND–2000–0006, by mail to Joel Singerman, Chief, Central New York Remediation Section, Emergency and Remedial Response Division, U.S. Environmental Protection Agency, Region 2, 290 Broadway, 20th Floor, New York, NY, 10007–1866. Comments may also be submitted electronically or through hand delivery/courier by following the detailed instructions in the "Addresses" section of the direct final rule located in the rules section of this **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Joel Singerman at the address noted in the **ADDRESSES** section; by telephone at 212–

637–4258; or by email at *singerman.joel@epa.gov.*

SUPPLEMENTARY INFORMATION: In the "Rules and Regulations" Section of today's **Federal Register**, EPA is publishing a direct final Notice of Deletion (NOD) of the Site without a prior NOID because EPA views this as a noncontroversial revision and anticipates no adverse comment. EPA has explained its reasons for this deletion in the preamble to the direct final NOD. If EPA receives no adverse comment(s) on this deletion action, EPA will proceed with the deletion without further action on this NOID. If EPA receives adverse comment(s), EPA will withdraw the direct final NOD, and it will not take effect. EPA will, as appropriate, address all public comments in a subsequent final NOD based on this NOID. EPA will not institute a second comment period on this NOID. Any parties interested in commenting must do so at this time.

For additional information, see the direct final NOD, which is located in the "Rules" section of this **Federal Register**.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous waste, Hazardous substances, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Authority: 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601–9675; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

Dated: August 2, 2016.

Judith A. Enck,

Regional Administrator, EPA Region.

[FR Doc. 2016–19142 Filed 8–11–16; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 10

RIN 0906–AA90

340B Drug Pricing Program; Administrative Dispute Resolution

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Health Resources and Services Administration (HRSA) implements section 340B of the Public Health Service Act (PHSA), which is referred to as the "340B Drug Pricing Program" or the "340B Program." This proposed rule will apply to all drug manufacturers and covered entities that participate in the 340B Program. The proposed rule sets forth the requirements and procedures for the 340B Program's administrative dispute resolution process.

DATES: Submit written comments on or before October 11, 2016.

ADDRESSES: You may submit comments, identified by the Regulatory Information Number (RIN) 0906–AA90, by any of the following methods. Please submit your comments in only one of these ways to minimize the receipt of duplicate submissions.

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow instructions for submitting comments. This is the preferred method for the submission of comments.
- *Email: 340BNPRMADR@hrsa.gov.* Include 0906–AA90 in the subject line of the message.
- *Regular, express, or overnight mail:* CAPT Krista Pedley, Director, Office of Pharmacy Affairs (OPA), Healthcare Systems Bureau (HSB), HRSA, 5600 Fishers Lane, Mail Stop 08W05A, Rockville, MD 20857. Please allow sufficient time for mailed comments to be received before the close of the comment period.

All submitted comments will be available to the public in their entirety. All comments received may be posted without change to *http://www.regulations.gov,* including any personally identifiable or confidential business information that is included in a comment.

FOR FURTHER INFORMATION CONTACT: CAPT Krista Pedley, Director, OPA, HSB HRSA, 5600 Fishers Lane, Mail Stop 08W05A, Rockville, MD 20857, or by telephone at 301–594–4353.

SUPPLEMENTARY INFORMATION: The President encourages Federal agencies through Executive Order 13563 to develop balanced regulations by encouraging broad public participation in the regulatory process and an open exchange of ideas. Accordingly, the Department of Health and Human Services (HHS or the Department) urges all interested parties to examine this regulatory proposal carefully and to share your views with us, including any data to support your positions. If you have questions before submitting comments, please see the **FOR FURTHER INFORMATION CONTACT** field above for the name and contact information of the subject-matter expert involved in the development of this proposal. We will consider all written comments received during the comment period before issuing a final rule.

If you are a person with a disability and/or a user of assistive technology who has difficulty accessing this document, please contact HRSA's Regulations Officer at: Room 13N82, 5600 Fishers Lane, Rockville, MD 20857; or by telephone at 301–443–1785, to obtain this information in an accessible format. This is not a toll free telephone number.

Please visit *http://www.HHS.gov/regulations* for more information on HHS rulemaking and opportunities to comment on proposed and existing rules.

I. Background

Section 602 of Public Law 102–585, the "Veterans Health Care Act of 1992," enacted section 340B of the PHSA entitled "Limitation on Prices of Drugs Purchased by Covered Entities," which was codified at 42 U.S.C. 256b. The 340B Program permits covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. REP. No. 102–384(II), at 12 (1992). The Secretary of the HHS delegated the authority to operate section 340B of the PHSA to the Administrator of HRSA. Pursuant to this delegation of authority, HRSA established and administers the 340B Program. Operationally, the 340B Program is housed within HRSA's Healthcare Systems Bureau (HSB), Office of Pharmacy Affairs (OPA). Eligible covered entity types are defined in section 340B(a)(4) of the PHSA, as amended. Section 340B of the PHSA instructs HHS to enter into pharmaceutical pricing agreements (PPA) with manufacturers of covered outpatient drugs. Manufacturers are required by section 1927(a)(5)(A) of the Social Security Act to enter into agreements with the Secretary of HHS that comply with section 340B of the PHSA if they participate in the Medicaid Drug Rebate Program. When a drug manufacturer signs a PPA, it agrees that the prices charged for covered outpatient drugs to covered entities will not exceed defined 340B ceiling prices, which are based on quarterly pricing data reported by manufacturers to the Centers for Medicare & Medicaid Services (CMS).

Section 7102 of the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by section 2302 of the Health Care and Education Reconciliation Act (Pub. L. 111–152), hereinafter referred to as the "Affordable Care Act," added section 340B(d)(3) of the PHSA, which requires the Secretary of HHS (or the Secretary) to promulgate a regulation establishing and implementing a binding administrative dispute resolution (ADR) process for certain disputes arising under the 340B Program. The purpose of the ADR process is to resolve (1) claims by covered entities that they have been overcharged for covered outpatient drugs by manufacturers; and (2) claims by manufacturers, after a manufacturer has conducted an audit as authorized by section 340B(a)(5)(C) of the PHSA, that a covered entity has violated the prohibition on diversion to ineligible patients or duplicate discounts. The 340B ADR process is not intended to be a trial-like proceeding governed by formal review of evidence and procedure. Rather, it is an administrative process that is designed to assist covered entities and manufacturers in resolving disputes regarding overcharging, duplicate discounts, or diversion. Historically, HHS has encouraged manufacturers and covered entities to work with each other to attempt to resolve disputes in good faith. The ADR process as proposed in this rule is not intended to replace these good faith efforts, but should be considered as a last resort in the event good faith efforts to resolve disputes have not been successful. In addition, covered entities and manufacturers should carefully evaluate whether the ADR process is appropriate for de minimis claims given the investment of the time and resources required of the parties involved.

In 2010, HHS issued an advanced notice of proposed rulemaking (ANPRM) that requested comments on the development of an ADR process (75 FR 57233, September 20, 2010). The ANPRM specifically requested comments on: (1) Administrative procedures, (2) existing models, (3) threshold requirements, (4) hearings, (5) decision-making officials or bodies, (6) appropriate appeals procedures, (7) deadlines, (8) discovery procedures, (9) manufacturer audits, (10) consolidation of manufacturer claims, (11) covered entity consolidation of claims; (12) claims by organizations representing covered entities, and (13) integration of dispute resolution with other 340B requirements added by the Affordable Care Act. HHS received 14 comments on the ANPRM. The comments received were considered in the development of this proposed rule.

HHS encourages all stakeholders to provide written comments on this NPRM. This proposed regulation, when finalized, will replace the 340B Program's guidelines on the informal dispute resolution process developed to resolve disputes between covered entities and manufacturers, which was published on December 12, 1996 (61 FR 65406).

II. Summary of the Proposed Regulations

The proposed revisions to 42 CFR part 10 are described according to the applicable section of the regulations. The United States District Court for the District of Columbia vacated the 340B Program Regulations at 42 CFR part 10 relating to Orphan Drugs (subpart C). (*PhRMA* v. *HHS, No. 13–01501 (D.D.C. May 23, 2014).* This NPRM proposes to add new definitions to § 10.3 and retitle and replace the language in subpart C as set forth below.

§ 10.3 Definitions.

HHS is proposing to add the following definitions: ''Administrative Dispute Resolution Process,'' ''Administrative Dispute Resolution Panel (340B ADR Panel),'' ''claim,'' and ''consolidated claim.''

Subpart C—Administrative Dispute Resolution

§ 10.20 340B Administrative Dispute Resolution Panel

(a) Members of the 340B ADR Panel.

As required by section 340B(d)(3)(B)(i), regulations promulgated by the Secretary shall designate or establish a decision-making official or body within HHS to review and make a binding decision for claims filed by covered entities and manufacturers. HHS proposes to establish a decision-making body (referred to as the ''340B ADR Panel'' or ''Panel'') to review and resolve such claims.

The proposed 340B ADR Panel will ensure an unbiased and fair review of the claims, and reduce the individual burden associated with having a single decision-making official who is solely responsible for reviewing and resolving claims. The proposed 340B ADR Panel will include three members, chosen from a roster of eligible individuals alternating from claim to claim, and one ex-officio, non-voting member chosen from the staff of OPA to facilitate the review and resolution of claims within a reasonable time frame. The proposed roster of eligible individuals will be comprised of Federal employees (*e.g.,* employees of CMS or the U.S. Department of Veterans Affairs) with demonstrated expertise or familiarity with the 340B Program. The ADR panel will not be compensated.

HHS proposes that for each filed claim that is reviewed, HSB will review the qualifications of individuals on the 340B ADR Panel roster and select those with expertise or familiarity with the appropriate aspects of the 340B Program. HHS also proposes that individuals serving on a 340B ADR Panel may be removed for cause. For example, if it is determined prior to or during the course of a Panel member's review of a claim that there is a conflict of interest, as described in subsection (b), with respect to that claim, the Panel member will be removed from the Panel and replaced by another individual from the 340B ADR Panel roster.

HHS is soliciting specific comments on the proposed size and composition of the 340B ADR Panel, in particular whether the 340B ADR Panel should be comprised of a set number of voting members to maintain consistency and transparency across each claim that is reviewed, whether HHS should retain the flexibility to appoint a requisite number of voting members based on the complexity of the claim and other factors, and whether the 340B ADR Panel should include at least one OPA staff member as a voting member or whether the inclusion of an OPA staff member as an ex-officio, non-voting member is sufficient to ensure adherence to 340B policies and procedures.

(b) Conflicts of interest.

To ensure fairness and objectiveness, HHS proposes that each 340B ADR Panel member be screened prior to reviewing a claim and not allowed to conduct a review if any conflicts of interest exist. For example, the individual would not review a claim if he or she has a conflict of interest with respect to the parties involved in the claim or the subject matter of the claim. HHS proposes that individuals be screened for conflicts of interest in accordance with U.S. Office of Government Ethics policies and procedures applicable to Federal employees. Conflicts of interest may include the following: (1) Financial interest; (2) family or close relation to a party involved; and (3) current or former business or employment relation to a party. The specific procedures for screening members of the panel prior to their service on the 340B ADR Panel will be detailed in future guidance.

(c) Duties of the 340B ADR Panel.

In subsection (c), HHS proposes that once the 340B ADR Panel receives the claim, the 340B ADR Panel will consider all documentation provided by the parties and may request additional information or clarification from any party involved with the claim. HHS also proposes that the 340B ADR Panel review claims in a session closed to the parties involved, including any associations or organizations, or legal counsel representing the parties.

In this subsection, HHS also proposes that the 340B ADR Panel may consult with subject matter experts within OPA regarding 340B program requirements while reviewing a claim. The 340B ADR Panel will provide a final decision only with respect to the claim. HHS proposes that the 340B ADR Panel's final decision must represent the decision of a majority of the Panel members but need not be unanimous.

§ 10.21 Claims

(a) Claims permitted.

Section 7102 of the Affordable Care Act added section 340B(d)(3) of the PHSA, which instructs the Secretary to establish and implement a binding ADR process to resolve certain 340B Program statutory violations. Section 340B(d)(3)(A) of the PHSA specifies that the ADR process is to be used to resolve: (1) Claims by covered entities that they have been overcharged by manufacturers for drugs purchased under this section and (2) claims by manufacturers, after a manufacturer has conducted an audit of a covered entity, as authorized by section 340B(a)(5)(C) of the PHSA, that a covered entity has violated the prohibitions against duplicate discounts and diversion (sections 340B(a)(5)(A) and (B) of the PHSA).

(b) Requirements for filing a claim.

In subsection (b), HHS proposes that the covered entity and the manufacturer meet certain requirements for filing a claim. These proposed requirements will ensure that a claim of the type specified in section 340B(d)(3)(A) of the PHSA is the subject of the dispute.

The Department is proposing that covered entities and manufacturers file a written claim, based on the facts available, to HSB within 3 years of the date of the sale (or payment) at issue in the alleged violation and that any claim not filed within 3 years shall be time barred. The proposed requirement that a claim be filed within 3 years is consistent with the record retention expectations for the 340B Program and will ensure that covered entities and manufacturers have access to relevant records needed to review and respond to claims. This proposal ensures documents must be submitted with each claim to verify that the alleged violation is not time barred. This proposed requirement will prevent a party from asserting a claim that is stale. HHS requests public comment concerning the 3 year limitation on claims submission.

HHS is also proposing that once a claim is submitted and the opposing party has been notified of the claim, any file, document, or record associated with a claim be maintained by the covered entity and/or manufacturer until the 340B ADR Panel's final agency decision is issued.

Covered Entity Claims

In section 10.21(b)(2), HHS proposes that to be eligible for the ADR process, each claim filed by a covered entity must include documents sufficient to demonstrate a covered entity's claim that it has been overcharged by a manufacturer, along with any such documentation as may be requested by HSB to evaluate the veracity of the claim. Such documentation may include: (1) A 340B purchasing account invoice which shows the purchase price by national drug code (NDC), less any taxes and fees; (2) the 340B ceiling price for the drug during the quarter(s) corresponding to the time period(s) of the claim; and (3) documentation of the attempts made to purchase the drug via a 340B account at the ceiling price, which resulted in the instance of overcharging. HHS believes that these documents are readily available to a covered entity through the usual course of business and should not be overly burdensome to produce, however HHS requests public comment on the feasibility or producing the documentation as proposed. HHS may also request that the covered entity provide it with a written summary of attempts to work in good faith to resolve the instance of overcharging with the manufacturer at issue.

Pursuant to section 340B(d)(1)(B) of the PHSA, HHS is developing a system to verify the ceiling price of a 340B drug and allow covered entities to access and verify the ceiling price. Until such system is developed, HHS has access to ceiling price data and will ensure that the 340B ADR panel will also have access as they evaluate any particular claim. Covered entities will be able to access ceiling price information through this system, which may lessen the burden in submitting the information accompanying a claim.

Manufacturer Claims

In section 10.21(b)(3), HHS proposes that to be eligible for the 340B ADR process, each claim filed by a manufacturer must include documents sufficient to demonstrate a manufacturer's claim that a covered entity has violated the prohibition on diversion and/or duplicate discount, along with any such documentation as may be requested by HSB to evaluate the veracity of the claim. Such documentation may include: (1) A final audit report which indicates that the manufacturer audited the covered entity for compliance with the prohibition on diversion (section 340B(a)(5)(B) of the PHSA) and/or duplicate discounts (section 340B(a)(5)(A) of the PHSA) and (2) the covered entity's written response to the manufacturer's audit finding(s). HHS may also request that the manufacturer submit a written summary of attempts to work in good faith to resolve the claim with the covered entity.

(c) Consolidation of claims.

In subsection (c), HHS proposes that, if requested, covered entities or manufacturers may be permitted to consolidate their individual claims. Section 340B(d)(3)(B)(vi) of the PHSA permits "multiple covered entities to jointly assert claims of overcharges by the same manufacturer for the same drug or drugs in one administrative proceeding. . . ." HHS proposes that for consolidated claims, the claim must list each covered entity and include documentation and/or information from each covered entity demonstrating that the covered entity meets all of the requirements for filing a claim with HHS and that a letter requesting consolidation of claims must also accompany the claim and must document that each covered entity consents to the consolidation of the claim.

Pursuant to section 340B(d)(3)(B)(vi) of the PHSA, consolidated claims are also permitted on behalf of covered entities by associations or organizations representing their interests. Therefore, HHS proposes that the covered entities must be members of the association or the organization representing them and that each covered entity must meet the requirements listed in subsection (b) for filing a claim with HSB. The proposed consolidated claim must assert overcharging by the same manufacturer for the same drug(s), and the organization or association will be responsible for filing the claim. HHS also proposes requiring that a letter requesting consolidation of claims must accompany the claim and must document that each covered entity consents to the organization or association asserting a claim on its behalf.

Similarly, at the request of two or more manufacturers, section 340B(d)(3)(B)(v) of the PHSA permits the consolidation of claims brought by more than one manufacturer against the same covered entity if consolidation is consistent with the statutory goals of fairness and economy of resources. This NPRM proposes that the claim must list each manufacturer and include documentation and/or information from each manufacturer demonstrating that the manufacturer meets the requirements listed in subsection (b) for filing a claim with HSB. HHS also proposes that a letter requesting consolidation of claims must be submitted with the claim and must document that each manufacturer consents to the consolidation of the claims. The statutory authority for implementing the 340B ADR process does not permit consolidated claims on behalf of manufacturers by associations or organizations representing their interests. Therefore, HHS is not proposing this option in this NPRM.

With regard to the consolidation of claims by manufacturers against a covered entity, HHS is seeking specific comment on the grounds under which consolidation would be consistent with the statutory goals of fairness and economy of resources, as required by section 340B(d)(3)(B)(v) of the PHSA. In addition, while HHS is proposing, as required by the 340B statute, an ADR process that allows manufacturers to consolidate claims against a covered entity, we recognize the operational challenges presented by the statutory requirement for a manufacturer to first audit the covered entity. HHS is, therefore, seeking comment on how manufacturers requesting a consolidated claim against a covered entity can satisfy the audit requirement.

(d) Deadlines and procedures for filing a claim.

In subsection (d), HHS proposes that covered entities and manufacturers file a claim with HSB demonstrating that they satisfy the requirements described in subsection (b) and that the party filing a claim must send written notice to the opposing party regarding the claim within 3 business days of submitting the claim and the party must submit confirmation of the opposing party's receipt or acknowledgement of receipt within 3 business days. HHS also proposes that the written notice to the opposing party must include a summary of the documents submitted as part of the claim.

HHS proposes that HSB will review the information submitted as part of the claim to verify that the requirements for filing a claim have been met. HSB would contact the initiating party once the claim has been received and may request additional information before accepting a claim for review by the 340B ADR Panel. If additional information is requested, the party filing the claim will have 20 business days of receipt of the request to respond. Claims will not move forward for review by the 340B ADR Panel if the initiating party does not respond to the request for additional information or if a party files a claim for any purpose other than those specified in the statute (*i.e.*, overcharging, duplicate discount, or diversion), or if the alleged violation occurred more than 3 years before the date of filing the claim.

HHS proposes that HSB will make a determination as to whether all requirements are met and provide written notice to all parties within 20 business days after receiving the claim and any subsequently requested information, which will be transmitted via both hard copy and email. If HSB determines the claim includes all necessary documentation and meets the requirements for filing a claim, the claim will be forwarded to the 340B ADR Panel for review. HSB would provide additional information on the 340B ADR process to all parties at that time, including contact information for requested follow-up communications and an approximate timeframe for the 340B ADR Panel's review.

HHS proposes that if the claim does not move forward for review by the ADR Panel, written notice will be sent by HSB to the parties involved that includes the basis for the decision and will advise the party that they may revise and refile the claim if the party has new information to support the alleged statutory violation.

(e) Responding to a submitted claim.

In subsection (e), HHS proposes that once the parties have been notified by HSB that the claim has met the requirements in subsection (b) and will move forward for review by the 340B ADR Panel, the opposing party will have 20 business days to submit a written response to the allegation to the 340B ADR Panel and the party who filed the claim. Subsequent requests for information regarding the claim would be made by the 340B ADR Panel as needed, and the 340B ADR Panel will consider any additional information that was provided by the parties involved. However, if an opposing party does not respond to a request for information from HSB or the 340B ADR Panel or otherwise elects not to participate in the 340B ADR process, the 340B ADR Panel will make a decision on the claim based on the information submitted in the claim.

§ 10.22 Covered entity information requests.

Pursuant to section 340B(d)(3)(B)(iii) of the PHSA, regulations promulgated by the Secretary for the 340B ADR process will establish procedures by which a covered entity may discover or obtain information and documents from manufacturers and third parties relevant to a claim that the covered entity has been overcharged by the manufacturer. This NPRM proposes that such covered entity information requests be facilitated by the 340B ADR Panel. HHS proposes that a covered entity must submit a written request for information to the 340B ADR Panel no later than 20 business days after the entity was notified by HSB that the claim would move forward for the ADR Panel's review. The 340B ADR Panel will review the information/document request to ensure that it is reasonable and within the scope of the asserted claim. The 340B ADR Panel will notify the covered entity in writing if any request is deemed reasonable and within the scope of the asserted claim and permit the covered entity to submit a revised information/document request, if it is not.

In this section, HHS proposes that the 340B ADR Panel will consider relevant factors, such as the scope of the information/document request, whether there are consolidated claims, or the involvement of one or more third parties in distributing drugs on behalf of the manufacturer and that once reviewed, the 340B ADR Panel will submit the information/document request to the manufacturer, which must respond within 20 business days.

HHS also proposes that the manufacturer must fully respond in writing to the information request and submit its response to the 340B ADR Panel by the stated deadline and that the manufacturer is responsible for obtaining relevant information/documents from wholesalers or other third parties that may facilitate sales or distribution of its drugs to covered entities. HHS proposes that if a manufacturer anticipates it will not be able to fully respond by the deadline, the manufacturer may request one extension in writing within 15 business days. The extension request that is submitted to the 340B ADR Panel must include any available information, the reason why the deadline is not feasible, and outline a proposed timeline for fully responding to the information request. The 340B ADR Panel will review the extension request and notify both the manufacturer and the covered entity in writing as to whether the request for an extension is granted and the date of the new deadline. If a manufacturer does not respond to a request for information from HSB or the 340B ADR Panel, HHS proposes that the 340B ADR Panel will make a decision on the claim based on the information submitted in the claim package that moved forward for review.

§ 10.23 Final agency decision

In § 10.23, HHS proposes that the 340B ADR Panel review the documents submitted by the parties and determine if there is adequate support to conclude that a violation as described in subsection (a)(1) or (2) of § 10.21 has occurred. The 340B ADR Panel will prepare a draft agency decision letter, which includes the 340B ADR Panel's findings and conclusions regarding the alleged violation. HHS is proposing a process whereby the 340B ADR Panel's draft agency decision letter will be sent to all parties, and the parties involved will have 20 business days to respond to the 340 ADR Panel. HHS is seeking specific comments on this process and whether this proposed process will facilitate or hinder the fair, efficient, and timely resolution of claims.

HHS also proposes that once the parties have reviewed and submitted comments to the draft agency decision letter, the 340B ADR Panel will prepare and submit its final agency decision letter to all parties in the dispute, which may incorporate rebuttals from the parties that were considered by the 340B ADR Panel to help inform the final agency decision. The final agency decision made by 340B ADR Panel will conclude the administrative resolution process; however, HHS proposes that the final agency decision letter also be submitted to HSB to take enforcement action or apply sanctions, as appropriate. For example, if the 340B ADR Panel makes a decision that a covered entity has violated the prohibition against diversion, HSB may require, as a sanction, that the covered entity repay the affected manufacturer. If the 340B ADR Panel makes a decision that a manufacturer overcharged a covered entity, HSB may require, as a sanction, that the manufacturer refund or issue a credit to the affected covered entity. In both cases, HSB will work with the party in violation on any remedy and corrective action.

HHS proposes that the 340B ADR Panel's final agency decision letter will be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction in accordance with section 340B(d)(3)(C) of the PHSA. HHS may, at its sole discretion, publish a summary of the claims that have gone through the 340B ADR process on the HRSA Web site, including the names of the parties and the nature of the 340B ADR Panel's findings (*e.g.,* overcharging, duplicate discount, or diversion). HHS will consider issuing future subregulatory guidance on this topic as necessary.

III. Regulatory Impact Analysis

HHS has examined the effects of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 8, 2011), the Regulatory Flexibility Act (September 19, 1980, Pub. L. 96–354), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132 on Federalism (August 4, 1999).

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866, emphasizing the importance of quantifying both costs and benefits, of reducing costs, harmonizing rules, and promoting flexibility. Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as "economically significant"); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. A regulatory impact analysis must be prepared for major rules with economically significant effects ($100 million or more in any one year), and a "significant" regulatory action is subject to review by the Office of Management and Budget (OMB).

This proposed rule is not likely to have economic impacts of $100 million or more in any one year; therefore, it has not been designated an "economically significant" rule under section 3(f)(1) of Executive Order 12866. This proposed rule creates a framework for the Department to resolve certain disputed claims regarding manufacturers overcharging covered entities and disputed claims of diversion and duplicate discounts by covered entities audited by manufacturers under the 340B Program. HHS does not anticipate the introduction of an administrative dispute resolution process to result in significant economic impacts.

The Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) and the Small Business Regulatory Enforcement and Fairness Act of 1996, which amended the RFA, require HHS to analyze options for regulatory relief of small businesses. If a rule has a significant economic effect on a substantial number of small entities, HHS must specifically consider the economic effect of the rule on small entities and analyze regulatory options that could lessen the impact of the rule. HHS will use an RFA threshold of at least a 3 percent impact on at least 5 percent of small entities.

The proposed rule would affect drug manufacturers (North American Industry Classification System code 325412: Pharmaceutical Preparation Manufacturing). The small business size standard for drug manufacturers is 750 employees. Approximately 600 drug manufacturers participate in the 340B Program. While it is possible to estimate the impact of the proposed rule on the industry as a whole, the data necessary to project changes for specific manufacturers or groups of manufacturers is not available, as HRSA does not collect the information necessary to assess the size of an individual manufacturer that participates in the 340B Program. The proposed rule would also affect health care providers. For purposes of the RFA, HHS considers all health care providers to be small entities either by virtue of meeting the Small Business Administration (SBA) size standard for a small business, or for being a nonprofit organization that is not dominant in its market. The current SBA size standard for health care providers ranges from annual receipts of $7 million to $35.5 million. As of July 1, 2016, over 12,000 covered entities participate in the 340B Program, which represent safety-net healthcare providers across the country.

The proposed rule introduces an administrative mechanism to review claims by manufacturers that covered entities have violated certain statutory obligations and claims by covered entities that have been overcharged for covered outpatient drugs by manufacturers. The documentation required as part of this administrative process are documents that manufacturers and covered entities are already required to maintain as part of their participation in the 340B Program. HHS expects that this documentation would be sufficiently available prior to submitting a claim. Therefore, the collection of this information would not result in an economic impact or create additional administrative burden on these businesses.

HHS believes the proposed administrative dispute resolution process will provide a cost-efficient option for resolving claims that would otherwise remain unresolved or require litigation. The proposed rule provides an option to consolidate claims by similar situated entities, and covered entities may have claims asserted on their behalf by associations or organizations which could reduce costs. HHS has determined, and the Secretary certifies that this final rule will not have a significant economic impact on a substantial number of small health care providers or a significant impact on the operations of a substantial number of small manufacturers; therefore we are not preparing an analysis of impact for the purposes of the RFA. HHS estimates that the economic impact on small entities and small manufacturers will be minimal and less than 3 percent. HHS welcomes comments concerning the impact of this proposed rule on small manufacturers and small health care providers.

Unfunded Mandates Reform Act

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year." In 2014, that threshold level was approximately $155 million. HHS does not expect this proposed rule to exceed the threshold.

Executive Order 13132—Federalism

HHS has reviewed this proposed rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have "federalism implications." This proposed rule would not "have substantial direct effects on the States, or on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." The proposals in this notice of proposed rulemaking, if implemented, would not adversely affect the following family elements: family safety, family stability, marital commitment; parental rights in the education, nurture, and supervision of their children; family functioning, disposable income, or poverty; or the behavior and personal responsibility of youth, as determined under section 654(c) of the Treasury and General Government Appropriations Act of 1999. HHS invites additional comments on the impact of this proposed rule from affected stakeholders.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that OMB approve all collections of information by a Federal agency from the public before they can be implemented. This proposed rule will not have a significant impact on the current reporting and recordkeeping burden for manufacturers or covered entities under the 340B Program. Based on current experience with the informal ADR process offered by the 340B Program, there have only been four requests for informal dispute resolution since the inception of the Program. Of the four dispute resolution requests, two were terminated by HRSA due to non-participation by one of the parties, another was dismissed due to lack of sufficient evidence, and the last was terminated because the parties disputed the existence of any attempt of good faith resolution. The relatively small number is attributed to the success of parties' attempts to resolve issues in good faith. Due to this very small number of informal dispute resolution requests, there has been very limited experience to date with dispute resolution record keeping. Changes proposed in this rulemaking would not result in significant reporting or recordkeeping burden. Comments are welcome on the accuracy of this statement.

Dated: May 24, 2016.

James Macrae,

Acting Administrator, Health Resources and Services Administration.

Approved: June 7, 2016.

Sylvia M. Burwell,

Secretary. Department of Health and Human Services.

List of Subjects in 42 CFR Part 10

Biologics, Business and industry, Diseases, Drugs, Health, Health care, Health facilities, Hospitals, 340B drug pricing program.

For the reasons set forth in the preamble, the Department of Health and Human Services proposes to amend 42 CFR part 10 as follows:

PART 10—340B DRUG PRICING PROGRAM

■ 1. The authority citation for part 10 is revised to read as follows:

Authority: Sec. 340B of the Public Health Service Act (42 U.S.C. 256b), as amended.

■ 2. Amend § 10.3 by adding definitions for "Administrative Dispute Resolution (ADR) process"," Administrative Dispute Resolution Panel (340B ADR Panel)", "Claim", and "Consolidated claim" to read as follows:

§ 10.3 Definitions.

* * * * *

Administrative Dispute Resolution (ADR) process means a process used to resolve claims by covered entities that may have been overcharged for 340B drugs purchased by manufacturers, and claims by manufacturers of 340B drugs, after a manufacturer has conducted an audit of a covered entity, that a covered entity may have violated the prohibitions against duplicate discounts or diversion.

Administrative Dispute Resolution Panel (340B ADR Panel) means a decision-making body within the Department that reviews and makes a binding decision for claims brought under the ADR Process.

* * * * *

Claim means an allegation made by or on behalf of a covered entity or by a manufacturer for purposes of the ADR Process.

Consolidated claim means the submittal of joint claims by covered entities (or their membership organization or association) or manufacturers to the 340B ADR Panel asserting the same allegation against the same party.

* * * * *

■ 3. Revise subpart C to read as follows:

Subpart C—Administrative Dispute Resolution

Sec.
10.20 Administrative Dispute Resolution Panel.
10.21 Claims.
10.22 Covered entity information requests.
10.23 Final agency decision.

§ 10.20 Administrative Dispute Resolution Panel.

The Secretary shall establish a decision-making body known as the Administrative Dispute Resolution Panel (340B ADR Panel) to review and make a binding final agency decision regarding claims filed by covered entities and manufacturers.

(a) *Members of the 340B ADR Panel.* (1) The Health Resources and Services Administration (HRSA) shall:

(A) Select three voting members of the 340B ADR Panel from a roster of eligible individuals and one ex-officio, non-voting member from the staff of HRSA's Office of Pharmacy Affairs (OPA);

(B) Alternate the individuals on the 340B ADR Panel for each claim;

(C) Remove an individual from the 340B ADR Panel for cause; and

(D) Appoint replacement members should an individual be unable to complete his or her duties.

(2) No member of the 340B ADR Panel may have a conflict of interest, as defined in subsection (b) of this section.

(b) *Conflicts of interest.* All members of the 340B ADR Panel will be screened for conflicts of interest prior to reviewing a claim. Conflicts of interest may include:

(1) Financial interest in a party involved, a subsidiary of a party involved, or in the claim before the 340B ADR Panel;

(2) Family or close relation to a party involved; and

(3) Current or former business or employment relation to a party.

(c) *Duties of the 340B ADR Panel.* The 340B ADR Panel will:

(1) Review and evaluate documents or information submitted by covered entities and manufacturers;

(2) Request additional information or clarification of an issue from any or all parties to make a final decision;

(3) Evaluate a claim in a separate session from the parties involved;

(4) Consult with OPA regarding any inquiries or concerns while reviewing a claim; and

(5) Make a final agency decision on each claim that will be communicated to HRSA for appropriate enforcement.

§ 10.21 Claims.

(a) *Claims permitted.* The ADR process is limited to the following:

(1) Claims by a covered entity that it has been overcharged, as defined in § 10.11(b), by a manufacturer for a covered outpatient drug; and

(2) Claims by a manufacturer, after it has conducted an audit of a covered entity pursuant to section 340B(a)(5)(C) of the PHSA, that the covered entity has violated section 340B(a)(5)(A) of the PHSA, regarding the prohibition of duplicate discounts, or section 340B(a)(5)(B) of the PHSA, regarding the prohibition of the resale or transfer of covered outpatient drugs to a person who is not a patient of the covered entity.

(b) *Requirements for filing a claim.* (1) A covered entity or manufacturer must file a claim for administrative dispute resolution in writing to HRSA within 3 years of the date of the alleged violation. Any file, document, or record associated with the claim that is the subject of a dispute must be maintained by the covered entity and manufacturer until the final agency decision letter is issued by the 340B ADR Panel.

(2) A covered entity filing a claim described in paragraph (a)(1) of this section must provide documents sufficient to demonstrate its claim that it has been overcharged by a manufacturer, along with any such other documentation as may be requested by HRSA.

(3) A manufacturer filing a claim under paragraph (a)(2) of this section must provide documents sufficient to demonstrate its claim that a covered entity has violated the prohibition on diversion and/or duplicate discount, along with any such documentation as may be requested by HRSA.

(c) *Consolidation of claims.* (1) Two or more covered entities may jointly file claims of overcharges by the same manufacturer for the same drug or drugs if each covered entity that could file a claim against the manufacturer consents to the jointly filed claim, and meets the minimum requirements, including submission of the required documentation, described in paragraph (b) of this section.

(2) An association or organization may file claims of overcharges by the same manufacturer for the same drug or drugs on behalf of multiple covered entities if each covered entity represented could file a claim against the manufacturer, is a member of the association or organization, meets the requirements described in paragraph (b) of this section, including submission of the required documentation, and each covered entity has agreed to representation by the association or organization on its behalf.

(3) A manufacturer or manufacturers may request to consolidate claims brought by more than one manufacturer against the same covered entity if each manufacturer could individually file a claim against the covered entity, consents to the jointly filed claim, meets the requirements described in paragraph (b) of this section for that claim, and the 340B ADR Panel determines that such consolidation is appropriate and consistent with the goals of fairness and economy of resources. The 340B ADR Panel will not permit joint claims filed on behalf of manufacturers by associations or organizations representing their interests.

(d) *Deadlines and procedures for filing a claim.* (1) Covered entities and manufacturers must file claims in writing to HRSA. A claim must include all of the requirements in paragraph (b) of this section. Additional information to substantiate a claim may be submitted.

(2) The party filing the claim must notify the opposing party in writing within 3 business days of the date the claim was filed and must provide documentation of such notification to HRSA. The written notice to the opposing party must include a summary of the documents submitted as part of the claim.

(3) HRSA will review all information submitted by the party filing the claim and will make a determination as to whether all requirements are met and provide written notice to all parties within 20 business days after receiving the claim and any subsequently requested information.

(A) *Claims that move forward for review.* If HRSA finds that the party filing the claim submitted all required documentation and thereby meets the requirements described in paragraph (b) of this section, written notification will be sent to both the manufacturer and covered entity advising that the claim will be forwarded to the 340B ADR Panel for review.

(B) *Claims that do not move forward for review.* If HRSA finds that the claim does not meet the requirements described in paragraph (b) of this section, written notification will be sent to both the manufacturer and covered entity detailing the reasons that the claim did not move forward. A claim will not move forward for review by the 340B ADR Panel if the claim does not meet the requirements in paragraph (b) of this section. That same claim may only be resubmitted if new information is presented to support the alleged statutory violation.

(e) *Responding to a submitted claim.* Upon receipt of notification that a claim will move forward to the 340B ADR Panel for review, the party in alleged violation will have 20 business days to submit a written response to the 340B ADR Panel. If an opposing party does not respond to a request for information from HRSA or the 340B ADR Panel, or elects not to participate in the 340B ADR process, the 340B ADR Panel will make a decision on the claim based on the information submitted in the claim. The 340B ADR Panel will consider any additional information that was provided by the parties involved.

§ 10.22 Covered entity information requests.

(a) A covered entity must submit a written request for additional information necessary to support its claim to the 340B ADR Panel within 20 business days of the claim acceptance date. The 340B ADR Panel will review the information request and notify the covered entity if the information request is beyond the scope of the claim and will permit the covered entity to resubmit a revised information request if necessary.

(b) The 340B ADR Panel will submit the covered entity's information request to the manufacturer who must respond to the request within 20 business days.

(c) The manufacturer must fully respond, in writing, to an information request from the 340B ADR Panel by the response deadline.

(1) A manufacturer is responsible for obtaining relevant information from any wholesaler or other third party that may facilitate the sale or distribution of its drugs to covered entities.

(2) If a manufacturer anticipates that it will not be able to respond to the information request by the deadline, it can request one extension by notifying the 340B ADR Panel in writing within 15 business days of receipt of the request.

(3) A request to extend the deadline must include the reason why the current deadline is not feasible and must outline the proposed timeline for fully responding to the information request.

(4) The 340B ADR Panel may approve or disapprove the request for an extension of time and will notify all parties in writing of its decision.

§ 10.23 Final agency decision.

(a) The 340B ADR Panel will review documents submitted by the parties and determine if there is adequate support to conclude that a violation as described in paragraph (a)(1) or (2) of § 10.21 has occurred.

(1) The 340B ADR Panel will prepare a draft agency decision letter based on its review and evaluation of all documents submitted by the parties, including documents provided as required in paragraph (b) of § 10.21, information requests in support of a claim, and responses to a claim.

(2) The draft agency decision letter will be sent to all parties and will include the 340B ADR Panel's preliminary findings regarding the alleged violation.

(3) All parties will have 20 business days to respond to the 340B ADR Panel's draft agency decision letter.

(b) The 340B ADR Panel will review the responses of all parties in producing the final agency decision letter.

(1) The final agency decision letter will represent the decision of a majority of the 340B ADR Panel's findings regarding the claim and discuss the findings supporting the decision.

(2) The 340B ADR Panel will submit the binding final agency decision letter to all parties, and to HRSA, as necessary, for appropriate enforcement action.

[FR Doc. 2016–18969 Filed 8–11–16; 8:45 am]

BILLING CODE 4165–15–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 97

[WT Docket No. 16–239; FCC 16–96]

Amateur Radio Service Rules To Permit Greater Flexibility in Data Communications

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Federal Communications Commission (Commission) seeks comment on proposed amendments regarding technical standards applicable to data communications that may be transmitted in the Amateur Radio Service. Specifically, we propose to remove limitations on the symbol rate (also known as the baud rate) applicable to data emissions in certain amateur bands. We believe that this rule change will allow amateur service licensees to use modern digital emissions, thereby better fulfilling the purposes of the amateur service and enhancing its usefulness.

DATES: Submit comments on or before October 11, 2016, and reply comments are due on or before November 10, 2016.

ADDRESSES: You may submit comments, identified by WT Docket No. 16–239, by any of the following methods:

- *Federal Communications Commission's Web site: http://apps.fcc.gov/ecfs/.* Follow the instructions for submitting comments.
- *Mail:* Federal Communications Commission, 445 12th Street SW., Washington, DC 20554.
- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432.

FOR FURTHER INFORMATION CONTACT: Scot Stone, *Scot.Stone@fcc.gov,* Wireless Telecommunications Bureau, (202) 418–0638, or TTY (202) 418–7233.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rulemaking (NPRM), adopted July 27, 2016 and released July 28, 2016. The full text of this document is available for public inspection and copying during regular business hours in the FCC Reference Center, Federal Communications Commission, 445 12th Street SW., Room CY–A257, Washington, DC 20554. The complete text may be purchased from the Commission's copy contractor, 445 12th Street, SW., Room CY–B402, Washington, DC 20554. This document will also be available via ECFS at *http://fjallfoss.fcc.gov/ecfs/.* Documents will be available electronically in ASCII, Microsoft Word, and/or Adobe Acrobat. Alternative formats are available for people with disabilities (Braille, large print, electronic files, audio format) by sending an email to *fcc504@fcc.gov* or calling the Commission's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

I. Introduction

1. In the *NPRM,* we propose, in response to a petition for rulemaking filed by the AmericanRadio Relay League, Inc. (ARRL), to amend part 97 of the Commission's rules regarding technical standards applicable to data communications that may be transmitted in the Amateur Radio Service. Specifically, we propose to remove limitations on the symbol rate (also known as baud rate)—the rate at which the carrier waveform amplitude, frequency, and/or phase is varied to transmit information—applicable to data emissions in certain amateur bands. We believe that this rule change will allow amateur service licensees to use modern digital emissions, thereby better fulfilling the purposes of the amateur service and enhancing its usefulness.

II. Background

2. The limitations on radioteletype (RTTY) and data transmissions below 450 MHz vary depending on the frequency band, and on whether the digital code used to encode the signal being transmitted is one of the codes specified in section 97.309(a) of the Commission's rules—Baudot, AMTOR, and ASCII (the "specified digital codes"). Section 97.307(f) limits the symbol rate for the specified digital codes, and the bandwidth for unspecified digital codes, as follows:

The specified digital codes may be used with a symbol rate not exceeding 300 bauds for frequencies below 28 MHz (except the 60 meter (5.3305–5.4064 MHz) band), and 1200 bauds in the 10 meter (28–29.7 MHz) band; in the 6 meter (50–54 MHz) and 2 meter (144–148 MHz) bands, the specified digital codes may be used with a symbol rate not exceeding 19.6 kilobauds, and unspecified digital codes may be used with a bandwidth not exceeding 20 kilohertz; in the 1.25 meter (219–225 MHz) and 70 centimeter (420–450 MHz) bands, the specified digital codes may be used with a symbol rate not exceeding 56 kilobauds, and unspecified digital codes may be used with a bandwidth not exceeding 100 kilohertz. An amateur station transmitting a RTTY or data emission using one of the specified digital codes may use any technique whose technical characteristics have been documented publicly, such as CLOVER, G–TOR, or PACTOR, for the purpose of facilitating communications.

III. Discussion

3. *Symbol rate limit.* We tentatively agree with ARRL that the baud rate limits should be eliminated, and propose to amend part 97 accordingly. As ARRL notes, digital emissions were "in their early stages and experimentation with them was limited" at that time, and "the state of the art in HF digital communications has advanced substantially" since then. Indeed, the Commission observed in 1993 that "as technology progresses the rules may become unnecessarily restrictive, particularly with regard to the permissible baud rate." For example, ARRL points out that PACTOR 3, which has a data rate of up to 3600 bits per second and a symbol rate of 100 bauds, is permitted in the HF bands; but PACTOR 4, which is capable of a data rate of 5800 bits per second without occupying any more spectrum, is prohibited at HF by the current rules because it has a symbol rate of 1800 bauds. Thus, ARRL argues, the current baud rate limits permit, if not actually encourage, inefficient spectrum utilization.

4. Many commenters agree that the baud rate restriction should be eliminated, and we seek comment on the reasons supporting such a view. For example, one commenter states that "part of the purpose of the amateur radio service is the advancement of radio and communications technology. Denying the ability to research and implement higher symbol rates directly contradicts the very purpose for amateur radio." Another commenter notes that "[t]he rest of the amateur radio operators in the world do not have this restrictive symbol rate requirement that is in the current part 97" and eliminating this restriction will allow the Emergency Communications Community to "benefit by being better able to meet its mission." Many commenters cite permitting PACTOR 4 at HF as a reason for changing the rule, particularly to facilitate more efficient transmission of emergency communications. Other commenters, however, are concerned that facilitating faster data throughput will actually increase congestion by encouraging the transmission of larger amounts of data and new types of content.

5. We tentatively agree that a baud rate restriction has become unnecessary due to advances in modulation techniques, and no longer serves a useful purpose. Our rules do not impose a symbol rate limit on data emissions in any other amateur bands or in any other radio service. In addition, removing the baud rate restriction could encourage individuals to more fully utilize the amateur service in experimentation and could promote innovation, more efficient use of the radio spectrum currently allocated to the amateur service, and the ability of the amateur service to support public safety efforts in the event of an emergency. Facilitating the ability of the amateur service to transmit and experiment with technologies currently used in consumer and commercial products furthers this goal. Consequently, we propose to remove the baud rate limits in section 97.307(f). We seek comment on this proposal. In particular, we seek comment on whether eliminating the baud rate limits would improve amateur communications, or would instead increase congestion. Regarding the likelihood that eliminating the baud rate limitation would increase congestion, we seek comment on whether the costs of such an increase are outweighed by the benefits that are likely to flow from the elimination of the limits, and whether there are ways to mitigate these costs without losing the benefits of the proposed initiative. More generally, we seek comment on whether there are other costs and benefits to the proposal and, when weighing all the factors, whether the benefits of the proposal outweigh its costs. Commenters opposed to eliminating the baud rate limits should also explain whether their concerns relate to all of the bands at issue, or only certain spectrum.

6. We decline, however, to propose to add a 2.8 kilohertz bandwidth limitation for RTTY and data emissions in the MF/HF bands as requested by the ARRL Petition. ARRL cites the 60 meter band as precedent for imposing a 2.8 kilohertz bandwidth limitation on data emissions, which ARRL states "would accommodate the HF data emissions that are in common use today." The commenters who support eliminating the baud rate restriction also generally agree with the ARRL's requested 2.8 kilohertz bandwidth limitation, but others who support eliminating the baud rate restriction favor a narrower bandwidth limitation in order to protect low-bandwidth modes of communication.

7. After reviewing the record, we tentatively conclude that a specific bandwidth limitation for RTTY and data emissions in the MF/HF bands is not necessary. We note that only the digital codes specified in section 97.309(a) may be used for MF/HF data emissions, and our rules do not impose any specific bandwidth limitation on use of the specified digital codes in any frequency band other than the 60 meter band. The 60 meter band cited by ARRL is a special case, however, given that amateur operators are permitted to operate only on specific frequencies rather than across the entire band, and are permitted to use only particular data and RTTY emission designators, in order to protect primary Federal voice operations in the band. Section 97.307(a) of the Commission's rules already provides that no amateur station transmission shall occupy more bandwidth than necessary for the information rate and emission type being transmitted, in accordance with good amateur practice, and section 97.307(c) already prohibits interference from spurious emissions (*i.e.,* emissions outside the necessary bandwidth). The methods to be used in calculating the necessary bandwidth of various emissions are specified in section 2.202 of the Commission's rules. We tentatively conclude that such rules are sufficient to help protect against inefficient use or other abuse of the spectrum identified by commenters, and will accomplish ARRL's stated reason for proposing a bandwidth limitation of facilitating sharing among amateur licensees.

8. We also observe that while a 2.8 kilohertz bandwidth limitation would accommodate HF data emissions that are in common use today, such a limitation could, at the same time, undermine the goal—fundamental to the amateur service—of encouraging advances in technology if amateur radio operators were thereby prevented from stepping beyond today's radio science. Imposing a maximum bandwidth would result in a loss of flexibility to develop

and improve technologies as licensees' operating interests change and new technologies are developed. We seek comment on these tentative conclusions.

9. While we tentatively conclude that a specific bandwidth limitation for RTTY and data emissions in the MF/HF bands is not necessary, we nonetheless request comment on whether we should establish emission bandwidth standards for amateur service MF/HF RTTY and data emissions. Commenters favoring such action should address what the maximum bandwidth should be, the basis for the particular limitation the commenter proposes, and whether the limit should apply across the bands or only in particular subbands. Commenters should explain the grounds for departing from the generally applicable standards.

IV. Conclusion

10. In summary, we believe that the public interest may be served by revising the amateur service rules to eliminate the current baud rate limitations for data emissions consistent with ARRL's Petition to allow amateur service licensees to use modern digital emissions, thereby furthering the purposes of the amateur service and enhancing the usefulness of the service. We do not, however, propose a bandwidth limitation for data emissions in the MF and HF bands to replace the baud rate limitations, because the rules' current approach for limiting bandwidth use by amateur stations using one of the specified digital codes to encode the signal being transmitted appears sufficient to ensure that general access to the band by licensees in the amateur service does not become unduly impaired.

V. Procedural Matters

11. *Initial Regulatory Flexibility Certification.* The Regulatory Flexibility Act (RFA) requires an initial regulatory flexibility analysis to be prepared for notice and comment rulemaking proceedings, unless the agency certifies that "the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities." The RFA generally defines the term "small entity" as having the same meaning as the terms "small business," "small organization," and "small governmental jurisdiction." In addition, the term "small business" has the same meaning as the term "small business concern" under the Small Business Act. A "small business concern" is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the Small Business Administration (SBA).

12. In the NPRM, we propose to amend the amateur service rules to change a technical rule applicable to data emissions that an amateur radio operator may use in his or her communications with other amateur radio operators. Because "small entities," as defined in the Regulatory Flexibility Act, do not include a "person" as the term is used in this proceeding or an individual, the proposed rules do not apply to "small entities." Rather, they apply exclusively to individuals who hold certain Commission authorizations. Therefore, we certify that the proposal in this NPRM, if adopted, will not have a significant economic impact on a substantial number of small entities.

13. *Paperwork Reduction Analysis.* This document does not contain proposed information collection(s) subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. In addition, therefore, it does not contain any new or modified information collection burden for small business concerns with fewer than 25 employees, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

VI. Ordering Clauses

14. *It is ordered* that, pursuant to Sections 4(i), 303(r), and 403 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 303(r), and 403, that this Notice of Proposed Rulemaking is *hereby adopted.*

15. *It is further ordered* that, pursuant to section 1.407 of the Commission's rules, 47 CFR 1.407, the Petition for Rulemaking, RM–11708, filed by the American Radio Relay League, Inc., on November 15, 2013 *is granted* to the extent indicated herein, and is otherwise *denied.*

16. *It is further ordered* that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of this Notice of Proposed Rulemaking, including the Initial Regulatory Flexibility Certification, to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects in 47 CFR Part 97

Radio.

Federal Communications Commission.

Gloria J Miles,

Federal Register Liaison Officer. Office of the Secretary.

Proposed Rules

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 97 as follows:

PART 97—AMATEUR RADIO SERVICE

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 48 Stat. 1066, 1082, as amended; 47 U.S.C. 154, 303. Interpret or apply 48 Stat. 1064–1068, 1081–1105, as amended; 47 U.S.C. 151–155, 301–609, unless otherwise noted.

■ 2. Section 97.305 is amended by revising the entry for 28.0–28.3 MHz in the table in paragraph (c) to read as follows:

§ 97.305 Authorized emission types.

* * * * *

(c) * * *

Wavelength band	Frequencies	Emission types authorized	Standards see § 97.307(f), paragraph:
* *	* *	* *	*
HF:			
* *	* *	* *	*
10 m	28.0–28.3 MHz	RTTY, data	(3).
* *	* *	* *	*

■ 3. Section 97.307 is amended by revising paragraph (f)(3), removing and reserving paragraph (f)(4), and revising paragraphs (f)(5) and (6) to read as follows:

§ 97.307 Emission standards.

* * * * *

(f) * * *

(3) Only an RTTY or data emission using a specified digital code listed in § 97.309(a) of this part may be transmitted.

(4) [Reserved]

(5) An RTTY, data or multiplexed emission using a specified digital code listed in § 97.309(a) of this part may be transmitted. An RTTY, data or multiplexed emission using an unspecified digital code under the limitations listed in § 97.309(b) of this part also may be transmitted, provided the bandwidth does not exceed 20 kHz.

(6) An RTTY, data or multiplexed emission using a specified digital code listed in § 97.309(a) of this part may be transmitted. An RTTY, data or multiplexed emission using an unspecified digital code under the limitations listed in § 97.309(b) of this part also may be transmitted, provided the bandwidth does not exceed 100 kHz.

* * * * *

[FR Doc. 2016–19085 Filed 8–11–16; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 20

[Docket No. FWS–HQ–MB–2016–0051; FF09M21200–156–FXMB1231099BPP0]

RIN 1018–BB40

Migratory Bird Hunting; Supplemental Proposals for Migratory Game Bird Hunting Regulations for the 2017–18 Hunting Season; Notice of Meetings

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; supplemental.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), proposed in an earlier document this year to establish annual hunting regulations for certain migratory game birds for the 2017–18 hunting season. This supplement to that proposed rule provides the regulatory alternatives for the 2017–18 duck hunting seasons, announces the Service Migratory Bird Regulations Committee (SRC) and Flyway Council meetings, and provides Flyway Council recommendations resulting from their March meetings.

DATES: *Comments:* We will accept comments on this proposed rule and any subsequent proposed rules resulting from upcoming SRC meetings until January 15, 2017.

Meetings: The SRC will meet to consider and develop proposed regulations for the 2017–18 migratory game bird hunting seasons on October 25–26, 2016. Meetings on both days will commence at approximately 8:30 a.m.

ADDRESSES: You may submit comments on the proposals by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments on Docket No. FWS–HQ–MB–2016–0051.
- *U.S. mail or hand-delivery:* Public Comments Processing, Attn: FWS–HQ–MB–2016–0051; Division of Policy, Performance, and Management Programs; U.S. Fish and Wildlife Service, MS: BPHC; 5275 Leesburg Pike, Falls Church, VA 22041.

We will not accept emailed or faxed comments. We will post all comments on *http://www.regulations.gov.* This generally means that your entire submission—including any personal identifying information—will be posted on the Web site. See the Public Comments section, below, for more information.

Meetings: The October 25–26, 2016, SRC meeting will be at the U.S. Fish and Wildlife Service, 5600 American Boulevard, Bloomington, MN 55437.

FOR FURTHER INFORMATION CONTACT: Ron W. Kokel at: Division of Migratory Bird Management, U.S. Fish and Wildlife Service, Department of the Interior, MS: MB, 5275 Leesburg Pike, Falls Church, VA 22041; (703) 358–1714.

SUPPLEMENTARY INFORMATION:

New Process for the Annual Migratory Game Bird Hunting Regulations

As part of the Department of the Interior's retrospective regulatory review, we developed a schedule for migratory game bird hunting regulations that is more efficient and provides hunting season dates much earlier than was possible under the old process. The new process makes planning much easier for the States and all parties interested in migratory bird hunting. Beginning last year with the development of the 2016–17 hunting seasons, we are using a new schedule for establishing our annual migratory game bird hunting regulations. We combine the previously used early- and late-season regulatory processes into a single process, and make decisions for harvest management based on predictions derived from long-term biological information and established harvest strategies to establish migratory bird hunting seasons much earlier than the system we used for many years. Under the new process, we develop proposed hunting season frameworks for a given year in the fall of the prior year. We then finalize those frameworks a few months later, thereby enabling the State agencies to select and publish their season dates in early summer. We provided a detailed overview of the new process in the June 10, 2016, **Federal Register** (81 FR 38050). This proposed rule is the second in a series of proposed and final rules for the establishment of the 2017–18 hunting seasons.

Service Migratory Bird Regulations Committee Meetings

The SRC will meet October 25–26, 2016, to review information on the current status of migratory game birds and develop 2017–18 migratory game bird regulations recommendations for these species. In accordance with Departmental policy, these meetings are open to public observation. You may submit written comments to the Service on the matters discussed.

Announcement of Flyway Council Meetings

Service representatives will be present at the individual meetings of the four Flyway Councils this August, September, and October. Although agendas are not yet available, these meetings usually commence at 8 a.m. on the days indicated.

Atlantic Flyway Council: October 6–7, 2016, Hyatt Regency, 225 East Coastline Drive, Jacksonville, FL.

Mississippi Flyway Council: August 25–26, 2016, Hyatt Regency, 311 South 4th Street, Louisville, KY.

Central Flyway Council: September 22–23, 2016, Sheraton Steamboat Resort, 2200 Village Inn Court, Steamboat Springs, CO.

Pacific Flyway Council: September 30, 2016, Sun Valley Resort, 1 Sun Valley Road, Sun Valley, ID.

Regulatory Schedule for 2017–18

On June 10, 2016, we published a proposal to amend title 50 of the Code of Federal Regulations (CFR) at part 20 (81 FR 38050). The proposal provided a background and overview of the migratory bird hunting regulations process, and addressed the establishment of seasons, limits, and other regulations for hunting migratory game birds under §§ 20.101 through 20.107, 20.109, and 20.110 of subpart K. This document is the second in a series of proposed, supplemental, and final rules for migratory game bird hunting regulations. We will publish additional supplemental proposals for public comment in the **Federal Register** as population, habitat, harvest, and other information become available. Major steps in the 2017–18 regulatory cycle relating to open public meetings and **Federal Register** notifications were illustrated in the diagram at the end of the June 10, 2016, proposed rule (81 FR 38050).

All sections of this and subsequent documents outlining hunting frameworks and guidelines are organized under the numbered headings set forth in the June 10, 2016, proposed rule (81 FR 38050). Later sections of this and subsequent documents will refer only to numbered items requiring your attention. Therefore, it is important to note that we will omit those items requiring no attention, and remaining numbered items will be discontinuous, thereby making the list appear incomplete.

The regulatory alternatives for the 2017–18 duck hunting seasons are contained at the end of this document. We plan to publish proposed season frameworks in mid-December 2016. We plan to publish final season frameworks in late February 2017.

Review of Public Comments

This proposed rulemaking describes recommended changes or specific preliminary proposals that vary from the 2016–17 regulations and issues requiring discussion, action, or the attention of the States or tribes. We will publish responses to all proposals and written comments when we develop final frameworks for the 2017–18 season. We seek additional information and comments on this supplemental proposed rule.

New proposals and modifications to previously described proposals are discussed below. Wherever possible, they are discussed under headings corresponding to the numbered items identified in the June 10, 2016, proposed rule (81 FR 38050). Only those categories requiring your attention or for which we received Flyway Council recommendations are discussed below.

1. Ducks

Duck harvest management categories are: (A) General Harvest Strategy; (B) Regulatory Alternatives, including specification of framework dates, season length, and bag limits; (C) Zones and Split Seasons; and (D) Special Seasons/Species Management.

A. General Harvest Strategy

Council Recommendations: The Mississippi Flyway Council recommended that regulation changes be restricted to one step per year, both when restricting as well as liberalizing hunting regulations.

Service Response: As we stated in the June 10, 2016, proposed rule (81 FR 38050), we intend to continue use of Adaptive Harvest Management (AHM) to help determine appropriate duck-hunting regulations for the 2017–18 season. AHM is a tool that permits sound resource decisions in the face of uncertain regulatory impacts, as well as providing a mechanism for reducing that uncertainty over time. The current AHM protocol is used to evaluate four alternative regulatory levels based on the population status of mallards and their breeding habitat (*i.e.,* abundance of ponds). Special hunting restrictions are enacted for certain species, such as canvasbacks, black ducks, scaup, and pintails.

Regarding the Mississippi Flyway Council recommendation to limit regulatory changes to one step per year, we recognize the longstanding interest by the Council to impose a one-step constraint on regulatory changes. We note that the Central and Mississippi Flyways have worked with Service staff over the past 2 years to re-visit the AHM protocol for managing harvest of mid-continent mallards (*i.e.,* "double-looping"). This effort has included a discussion of appropriate management objectives, regulatory packages, and management of non-mallard stocks. We continue to believe that these discussions are the appropriate venue to discuss what role, if any, a one-step constraint might play in management of waterfowl in the Central and Mississippi Flyways. Such discussions should include the potential impact of a one-step constraint on the frequency of when the liberal, moderate, and restrictive packages would be recommended. On a final note, while we recognize the Council's concern about potentially communicating a large regulatory change to hunters, we have concerns about the appropriateness of a one-step constraint in situations when the status of the waterfowl resource may warrant such a measure. We look forward to continued work with the Flyway Councils on this issue.

B. Regulatory Alternatives

Council Recommendations: The Mississippi and Central Flyway Councils recommended that regulatory alternatives for duck hunting seasons remain the same as those used in 2016–17. The Mississippi Flyway Council further recommended changing the framework closing date to January 31 during "moderate" and "liberal" seasons.

Service Response: As we stated in a final rule published earlier this year (81 FR 17302, March 28, 2016), we do not support the Council's recommendation to extend the duck season framework closing date to January 31 at this time. We note that the current framework opening and closing dates were developed through a cooperative effort between all four Flyway Councils and that framework dates are only one of several components that comprise the regulatory packages utilized in AHM. Regulatory packages also consider season length, daily bag limits, and shooting hours. We believe the current regulatory packages in the Atlantic and Mississippi Flyways should remain unchanged until revisions to the AHM protocols have been completed. Those efforts will include examination of duck harvest management objectives, model updates, and revisions to regulatory packages, including framework dates. We prefer that the issue of framework dates and any other component of the regulatory packages be addressed through this cooperative process and would prefer a comprehensive approach to revising regulatory packages rather than making incremental changes.

Thus, the regulatory alternatives proposed in the June 10, 2016, **Federal Register** (81 FR 38050) will be used for the 2017–18 hunting season (see accompanying table at the end of this document for specific information). In 2005, the AHM regulatory alternatives were modified to consist only of the maximum season lengths, framework dates, and bag limits for total ducks and mallards. Restrictions for certain species within these frameworks that are not covered by existing harvest strategies will be addressed in the proposed frameworks rule in early December. For those species with specific harvest strategies (pintails, black ducks, and scaup), those strategies will again be used for the 2017–18 hunting season.

D. Special Seasons/Species Management

iv. Canvasbacks

Council Recommendations: The Central Flyway Council recommends a 2-bird canvasback daily bag when populations are above 480,000, a 1-bird daily bag limit when between 460,000–480,000, and a closed season when below 460,000.

16. Mourning Doves

Council Recommendations: The Atlantic and Mississippi Flyway Councils recommended that the framework closing date for mourning doves in the Eastern Management Unit be moved from January 15 to January 31 for the 2017–18 hunting season.

Public Comments

The Department of the Interior's policy is, whenever practicable, to afford the public an opportunity to participate in the rulemaking process. Accordingly, we invite interested persons to submit written comments, suggestions, or recommendations regarding the proposed regulations. Before promulgation of final migratory game bird hunting regulations, we will take into consideration all comments we receive. Such comments, and any additional information we receive, may lead to final regulations that differ from these proposals.

You may submit your comments and materials concerning the proposed rule by one of the methods listed in **ADDRESSES**. We will not accept comments sent by email or fax or to an address not listed in **ADDRESSES**. Finally, we will not consider hand-delivered comments that we do not receive, or mailed comments that are not postmarked, by the date specified in **DATES**. We will post all comments in their entirety—including your personal identifying information—on *http://www.regulations.gov*. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. Comments and materials we receive, as well as supporting documentation we used in preparing the proposed rule, will be available for public inspection on *http://www.regulations.gov,* or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Division of Migratory Bird Management, 5275 Leesburg Pike, Falls Church, VA.

We will consider, but possibly may not respond in detail to, each comment. As in the past, we will summarize all comments we receive during the comment period and respond to them after the closing date in any final rules.

Required Determinations

Based on our most current data, we are affirming our required determinations made in the June 10, 2016, proposed rule (81 FR 38050); for descriptions of our actions to ensure compliance with the following statutes and Executive Orders, see that document:

- National Environmental Policy Act;
- Endangered Species Act;
- Regulatory Flexibility Act;
- Small Business Regulatory Enforcement Fairness Act;
- Paperwork Reduction Act;
- Unfunded Mandates Reform Act; and
- Executive Orders 12630, 12866, 12988, 13132, 13175, 13211, and 13563.

List of Subjects in 50 CFR Part 20

Exports, Hunting, Imports, Reporting and recordkeeping requirements, Transportation, Wildlife.

Authority

The rules that eventually will be promulgated for the 2017–18 hunting season are authorized under 16 U.S.C. 703–711, 16 U.S.C. 712, and 16 U.S.C. 742 a–j.

Dated: August 2, 2016.

Karen Hyun,

Acting Principal Deputy Assistant Secretary for Fish and Wildlife and Parks.

REGULATORY ALTERNATIVES FOR DUCK HUNTING DURING THE 2017-18 SEASON

	ATLANTIC FLYWAY			MISSISSIPPI FLYWAY			CENTRAL FLYWAY (a)			PACIFIC FLYWAY (b)(c)		
	RES	MOD	LIB	RES	MOD	LIB	RES	MOD	LIB	RES	MOD	LIB
Beginning Shooting Time	1/2 hr. before sunrise	1/2 hr. before sunrise	1/2 hr. before sunrise	1/2 hr. before sunrise	1/2 hr. before sunrise	1/2 hr. before sunrise	1/2 hr. before sunrise	1/2 hr. before sunrise	1/2 hr. before sunrise	1/2 hr. before sunrise	1/2 hr. before sunrise	1/2 hr. before sunrise
Ending Shooting Time	Sunset	Sunset	Sunset	Sunset	Sunset	Sunset	Sunset	Sunset	Sunset	Sunset	Sunset	Sunset
Opening Date	Oct. 1	Sat. nearest Sept. 24	Sat. nearest Sept. 24	Sat. nearest Oct. 1	Sat. nearest Sept. 24	Sat. nearest Sept. 24	Sat. nearest Oct. 1	Sat. nearest Sept. 24	Sat. nearest Sept. 24	Sat. nearest Oct. 1	Sat. nearest Sept. 24	Sat. nearest Sept. 24
Closing Date	Jan. 20	Last Sunday in Jan.	Last Sunday in Jan.	Sun. nearest Jan. 20	Last Sunday in Jan.	Last Sunday in Jan.	Sun. nearest Jan. 20	Last Sunday in Jan.	Last Sunday in Jan.	Sun. nearest Jan. 20	Last Sunday in Jan.	Last Sunday in Jan.
Season Length (in days)	30	45	60	30	45	60	39	60	74	60	86	107
Daily Bag	3	6	6	3	6	6	3	6	6	4	7	7
Species/Sex Limits within the Overall Daily Bag Limit												
Mallard (Total/Female)	3/1	4/2	4/2	2/1	4/1	4/2	3/1	5/1	5/2	3/1	5/2	7/2

(a) In the High Plains Mallard Management Unit, all regulations would be the same as the remainder of the Central Flyway, with the exception of season length. Additional days would be allowed under the various alternatives as follows: restrictive - 12, moderate and liberal - 23. Under all alternatives, additional days must be on or after the Saturday nearest December 10.

(b) In the Columbia Basin Mallard Management Unit, all regulations would be the same as the remainder of the Pacific Flyway, with the exception of season length. Under all alternatives except the liberal alternative, an additional 7 days would be allowed.

(c) In Alaska, framework dates, bag limits, and season length would be different from the remainder of the Pacific Flyway. The bag limit (depending on the area) would be 5-8 under the restrictive alternative, and 7-10 under the moderate and liberal alternatives. Under all alternatives, season length would be 107 days and framework dates would be Sep. 1 - Jan. 26.

[FR Doc. 2016–19221 Filed 8–11–16; 8:45 am]

BILLING CODE 4333–15–P

Notices

Federal Register
Vol. 81, No. 156
Friday, August 12, 2016

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Office of the Secretary

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Principles on Industrial Hemp

AGENCY: Office of the Secretary, USDA; Drug Enforcement Administration, DOJ; Food and Drug Administration, HHS.

ACTION: Notice

SUMMARY: The U.S. Department of Agriculture, in consultation with the U.S. Drug Enforcement Administration and the U.S. Food and Drug Administration, has developed a *Statement of Principles on Industrial Hemp* to inform the public how Federal law applies to activities associated with industrial hemp that is grown and cultivated in accordance with Section 7606 of the Agricultural Act of 2014. The purpose of this notice is to set forth the statement in its entirety.

DATES: This Statement of Principles is applicable August 12, 2016.

FOR FURTHER INFORMATION CONTACT: Michael Poe, Telephone Number: (202) 720–3257.

SUPPLEMENTARY INFORMATION:

1. Statement of Principles

With publication of this notice, the U.S. Department of Agriculture (USDA) issues, with the concurrence of the U.S. Drug Enforcement Administration (DEA) and the U.S. Food and Drug Administration (FDA), the following Statement of Principles regarding the applicability of Federal laws to activities associated with growing and cultivating industrial hemp:

Section 7606 of the Agricultural Act of 2014 legalized the growing and cultivating of industrial hemp for research purposes in States where such growth and cultivation is legal under State law, notwithstanding existing Federal statutes that would otherwise criminalize such conduct. The statutorily sanctioned conduct, however, was limited to growth and cultivation by an institution of higher education or State department of agriculture for purposes of agricultural or other academic research or under the auspices of a State agricultural pilot program for the growth, cultivation, or marketing of industrial hemp.

Section 7606 authorized State departments of agriculture to promulgate regulations to carry out these pilot programs but did not provide a specific delegation to the U.S. Department of Agriculture (USDA) or any other agency to implement the program. As well, the statute left open many questions regarding the continuing application of Federal drug control statutes to the growth, cultivation, manufacture, and distribution of industrial hemp products, as well as the extent to which growth by private parties and sale of industrial hemp products are permissible. Section 7606 did not remove industrial hemp from the controlled substances list. Therefore, Federal law continues to restrict hemp-related activities, to the extent that those activities have not been legalized under section 7606.

USDA, having consulted with and received concurrence from the U.S. Drug Enforcement Administration (DEA) and the U.S. Food and Drug Administration (FDA), therefore, is issuing this statement of principles to inform the public regarding how Federal law applies to activities involving industrial hemp so that individuals, institutions, and States that wish to participate in industrial hemp agricultural pilot programs can do so in accordance with Federal law.

- The growth and cultivation of industrial hemp may only take place in accordance with an agricultural pilot program to study the growth, cultivation, or marketing of industrial hemp established by a State department of agriculture or State agency responsible for agriculture in a State where the production of industrial hemp is otherwise legal under State law.
- The State agricultural pilot program must provide for State registration and certification of sites used for growing or cultivating industrial hemp. Although registration and certification is not further defined, it is recommended that such registration should include the name of the authorized manufacturer, the period of licensure or other time period during which such person is authorized by the State to manufacture industrial hemp, and the location, including Global Positioning System coordinates, where such person is authorized to manufacture industrial hemp.
- Only State departments of agriculture, and persons licensed, registered, or otherwise authorized by them to conduct research under an agricultural pilot program in accordance with section 7606, and institutions of higher education (as defined in section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001)), or persons employed by or under a production contract or lease with them to conduct such research, may grow or cultivate industrial hemp as part of the agricultural pilot program.
- The term "industrial hemp" includes the plant *Cannabis sativa* L. and any part or derivative of such plant, including seeds of such plant, whether growing or not, that is used exclusively for industrial purposes (fiber and seed) with a tetrahydrocannabinols concentration of not more than 0.3 percent on a dry weight basis. The term "tetrahydrocannabinols" includes all isomers, acids, salts, and salts of isomers of tetrahydrocannabinols.
- For purposes of marketing research by institutions of higher education or State departments of agriculture (including distribution of marketing materials), but not for the purpose of general commercial activity, industrial hemp products may be sold in a State with an agricultural pilot program or among States with agricultural pilot programs but may not be sold in States where such sale is prohibited. Industrial hemp plants and seeds may not be transported across State lines.
- Section 7606 specifically authorized certain entities to "grow or cultivate" industrial hemp but did not eliminate the requirement under the Controlled Substances Import and

Export Act that the importation of viable cannabis seeds must be carried out by persons registered with the DEA to do so. In addition, any USDA phytosanitary requirements that normally would apply to the importation of plant material will apply to the importation of industrial hemp seed.

- Section 7606 did not amend the Federal Food, Drug, and Cosmetic Act. For example, section 7606 did not alter the approval process for new drug applications, the requirements for the conduct of clinical or nonclinical research, the oversight of marketing claims, or any other authorities of the FDA as they are set forth in that Act.
- The Federal Government does not construe section 7606 to alter the requirements of the Controlled Substances Act (CSA) that apply to the manufacture, distribution, and dispensing of drug products containing controlled substances. Manufacturers, distributors, dispensers of drug products derived from cannabis plants, as well as those conducting research with such drug products, must continue to adhere to the CSA requirements.
- Institutions of higher education and other participants authorized to carry out agricultural pilot programs under section 7606 may be able to participate in USDA research or other programs to the extent otherwise eligible for participation in those programs.

2. Regulatory Requirements

This Statement of Principles does not establish any binding legal requirements. It is, therefore, exempt from notice and comment rulemaking requirements under the Administrative Procedure Act pursuant to 5 U.S.C. 553(b). Because no notice of proposed rulemaking is required, the Regulatory Flexibility Act does not require an initial or final regulatory flexibility analysis. 5 U.S.C. 603(a), 604(a). USDA has determined that this Statement of Principles does not impose any new or revise any existing recordkeeping, reporting, or disclosure requirements on covered entities or members of the public that would be collections of information requiring OMB approval under the Paperwork Reduction Act, 44 U.S.C. 3501, *et seq.*

Dated: July 25, 2016.

Thomas J. Vilsack,

Secretary of Agriculture.

Dated: July 21, 2016.

Louis J. Milione,

Deputy Assistant Administrator, Drug Enforcement Administration.

Dated: July 22, 2016.

Leslie Kux,

Associate Commissioner for Policy, Food and Drug Administration.

[FR Doc. 2016–19146 Filed 8–11–16; 8:45 am]

BILLING CODE 3410–01–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2016–0043]

Okanagan Specialty Fruits, Inc.; Availability of Preliminary Finding of No Significant Impact, Preliminary Plant Pest Risk Similarity Assessment, and Preliminary Determination for an Extension of a Determination of Nonregulated Status for Non-Browning Arctic® Apple Event NF872 Apple

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service has reached a preliminary decision to extend our determination of nonregulated status of Okanagan Specialty Fruits' (OSF) GS784 and GD743 apples to OSF NF872 'Arctic® Fuji apple'. OSF's NF872 apple has been genetically engineered for enzymatic browning resistance using the same mode of action as GS784 and GD743 apples. We are making available for public comment our preliminary determination, preliminary plant pest risk similarity assessment, and preliminary finding of no significant impact for the proposed determination of nonregulated status.

DATES: We will consider all comments that we receive on or before September 12, 2016.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0043.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2016–0043, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

The Okanagan Specialty Fruits extension request, our preliminary determination, preliminary plant pest risk similarity assessment, preliminary finding of no significant impact, and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0043* or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

Supporting documents and any comments we received regarding our determination of nonregulated status of the antecedent organisms (apple events GD743 and GS784), can be found at *http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0025.* Supporting documents may also be found on the APHIS Web site for NF872 'Arctic® Fuji apple' (the organism under evaluation) under APHIS Petition Number 16–004–01p, and the antecedent organisms (apple events GD743 and GS784) under APHIS Petition Number 10–161–01p.

FOR FURTHER INFORMATION CONTACT: Dr. John Turner, Director, Biotechnology Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737–1236; (301) 851–3954, email: *john.t.turner@aphis.usda.gov.* To obtain copies of the supporting documents, contact Ms. Cindy Eck at (301) 851–3885, email: *cynthia.a.eck@aphis.usda.gov.*

SUPPLEMENTARY INFORMATION: Under the authority of the plant pest provisions of the Plant Protection Act (PPA) (7 U.S.C. 7701 *et seq.*), the regulations in 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests," regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered organisms and products are considered "regulated articles."

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. Further, the regulations in § 340.6(e)(2) provide that a person may request that APHIS extend a determination of nonregulated status to other organisms. Such a request must include information to establish the similarity of the antecedent organism and the regulated article in question.

In a notice[1] published in the **Federal Register** on November 8, 2013 (78 FR 67100, Docket No. APHIS–2012–0025), APHIS announced our determination of nonregulated status of apples (*Malus domestica*) designated as events GD743 and GS784, which have been genetically engineered to resist browning. APHIS has received a request for an extension of a determination of nonregulated status of GD743 and GS784 apples to Arctic® apple event NF872 (hereinafter NF872 apple) (APHIS Petition Number 16–004–01p) from Okanagan Specialty Fruits, Inc. (hereinafter referred to as OSF), of British Columbia, Canada. In the extension request, OSF named the two previously deregulated apple events as antecedents. Like the antecedents, NF872 apple is genetically engineered to be resistant to enzymatic browning. In its request, OSF stated that NF872 apple was produced by transforming an additional variety of apple using the same DNA and method that was used for the antecedent apples and, based on the similarity, is unlikely to pose a plant pest risk. Therefore, the request stated that NF872 apple should not be a regulated article under APHIS' regulations in 7 CFR part 340.

As described in the extension request, NF872 apple has been genetically engineered through the insertion of genetic elements from apples. APHIS has previously assessed the risks associated with the insertion of these same genetic elements into apples and concluded that the resulting organisms did not pose a plant pest risk. Based on the information in the request, we have concluded that NF872 apple is similar to the antecedent apples. NF872 apple is currently regulated under 7 CFR part 340.

As part of our decisionmaking process regarding a genetically engineered organism's regulatory status, APHIS evaluates the plant pest risk of the article. In section 403 of the PPA, "plant pest" is defined as any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant product: A protozoan, a nonhuman animal, a parasitic plant, a bacterium, a fungus, a virus or viroid, an infectious agent or other pathogen, or any article similar to or allied with any of the foregoing.

APHIS completed a plant pest risk assessment (PPRA) for the antecedent organisms in which we concluded that the GD743 and GS784 apples are unlikely to present a plant pest risk. NF872 apple expresses the same resistance to enzymatic browning as the antecedent apples. Therefore, based on our PPRA for the antecedents and the similarity between NF872 apple and the antecedents, APHIS has concluded that NF872 apple is unlikely to pose a plant pest risk. APHIS also prepared a plant pest risk similarity assessment (PPRSA) to compare NF872 to the antecedents. As described in the PPRSA, the NF872 apple was obtained using a polyphenol oxidase (PPO) suppression construct designed to reduce the expression of four apple genes coding for PPO proteins. The PPO suppression construct used in the NF872 apple event is the same construct used in the antecedent apple events GD743 and GS784, and APHIS has concluded that the PPO suppression construct used in GD743 and GS784 is unlikely to affect the plant pest risk of NF872. Furthermore, APHIS has previously reviewed the potential impacts on non-target organisms beneficial to agriculture and concluded that it is unlikely that NF872 apple will have an adverse effect on nontarget organisms. Therefore, based on our PPRA for GD743 apple and GS784 apple and the similarity between GD743 apple, GS784 apple, and NF872 apple as described in the PPRSA, APHIS has concluded that the PPO suppression construct used to obtain the NF872 apple is unlikely to pose a plant pest risk and that NF872 apple is unlikely to pose a different plant pest risk than GD743 apple and GS784 apple.

The environmental assessment (EA) for the antecedent organisms was prepared using data submitted by OSF, a review of other scientific data, and field tests conducted under APHIS oversight. The EA was prepared to provide the APHIS decisionmaker with a review and analysis of any potential environmental impacts associated with the proposed determination of nonregulated status of the antecedent apples. The EA was prepared in accordance with (1) the National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*); (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508); (3) USDA regulations implementing NEPA (7 CFR part 1b); and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Based on the similarity of NF872 apple to the antecedent apples, APHIS has prepared a preliminary finding of no significant impact (FONSI) on NF872 apple using the EA prepared for GD743 and GS784 apples. APHIS considered the following alternatives: (1) Take no action, *i.e.*, APHIS would not change the regulatory status of NF872 apple and it would continue to be a regulated article, or (2) make a determination of nonregulated status of NF872 apple. APHIS' preferred alternative is to make a determination of nonregulated status of NF872 apple.

APHIS has carefully examined the existing NEPA documentation completed for GD743 and GS784 apples and has concluded that OSF's request to extend a determination of nonregulated status to NF872 apple encompasses the same scope of environmental analysis as the antecedent apples.

Based on APHIS' analysis of information submitted by OSF, references provided in the extension request, peer-reviewed publications, information analyzed in the EA, and the similarity of NF872 apple to the antecedent organisms, APHIS has determined that NF872 apple is unlikely to pose a plant pest risk. We have therefore reached a preliminary decision to approve the request to extend the determination of nonregulated status of GD743 and GS784 apples to NF872 apple, whereby NF872 apple would no longer be subject to our regulations governing the introduction of certain genetically engineered organisms.

Paragraph (e) of § 340.6 provides that APHIS will publish a notice in the **Federal Register** announcing all preliminary decisions to extend determinations of nonregulated status for 30 days before the decisions become final and effective. In accordance with § 340.6(e) of the regulations, we are publishing this notice to inform the public of our preliminary decision to extend the determination of nonregulated status of the antecedent apples to NF872 apple.

APHIS will accept written comments on the preliminary FONSI regarding a determination of nonregulated status of NF872 apple for a period of 30 days from the date this notice is published in the **Federal Register**. The preliminary FONSI, as well as the extension request, supporting documents, and our preliminary determination for NF872 apple, are available for public review as indicated under **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT** above. Copies of these documents may also be obtained by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

After the comment period closes, APHIS will review all written comments received during the comment period and any other relevant information. All comments will be available for public review. After reviewing and evaluating the comments, if APHIS determines that no substantive information has been received that would warrant APHIS altering its preliminary regulatory determination or FONSI, our preliminary regulatory determination will become final and effective upon notification of the public through an announcement on our Web site at *http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml.* APHIS will also furnish a response to the petitioner regarding our final regulatory determination. No further **Federal Register** notice will be published announcing the final regulatory determination regarding NF872 apple.

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[1] To view the notice, our determination, supporting documents, and the comments we have received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0025*.

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 8th day of August 2016.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2016–19222 Filed 8–11–16; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2016–0031]

Environmental Impact Statement; Fruit Fly Eradication Program

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service plans to prepare an updated environmental impact statement to analyze the effects of a program to eradicate exotic fruit fly species from wherever they might occur in the United States, including Hawaii, Guam, American Samoa, Puerto Rico, and the U.S. Virgin Islands. This notice identifies potential issues and alternatives that will be studied in the environmental impact statement, and requests public comments to further delineate the scope of the alternatives and environmental impacts and issues.

DATES: We will consider all comments that we receive on or before September 26, 2016.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0031.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2016–0031, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0031* or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For questions related to the Fruit Fly Eradication Program, contact Mr. John C. Stewart, APHIS National Fruit Fly Eradication Program Manager, Center for Plant Health Science and Technology, PPQ, APHIS, 1730 Varsity Drive, Suite 400, Raleigh NC 27606, *John.C.Stewart@aphis.usda.gov;* (919) 855–7426. For questions related to the environmental impact statement, contact Dr. Jim Warren, Environmental Protection Specialist, Environmental and Risk Analysis Services, PPD, APHIS, 4700 River Road, Unit 149, Riverdale, MD 20737; *Jim.E.Warren@aphis.usda.gov;* (202) 316–3216.

SUPPLEMENTARY INFORMATION:

Background

Non-native (exotic) fruit flies in the family Tephritidae have a wide host range, including more than 400 species of fruit and vegetables. Introduction of these pest species into the United States causes economic losses from destruction and spoiling of host commodities by larvae, costs associated with implementing control measures, environmental impacts due to increased pesticide usage if fruit flies become established, and loss of market share due to restrictions on shipment of host commodities. Three species pose the greatest risk to United States agriculture: the Mediterranean fruit fly (Medfly), *Ceratitis capitata;* the Oriental fruit fly (OFF), *Bactrocera dorsalis;* and the Mexican fruit fly (Mexfly), *Anastrepha ludens.*

Currently, Medfly is established in Hawaii where it was first detected in 1910. Although Medfly has been periodically introduced to the United States mainland since 1929, successful eradication programs have prevented it from becoming an established pest in the continental United States. OFF was introduced into Hawaii in the 1940s and has since became established there. Although OFF is not established in the continental United States, new infestations have been detected on an almost annual basis since it was first detected in California in 1960. The Mexfly has been introduced repeatedly to Texas and eradicated since its first introduction in 1927. The risk of introduction along the Mexican and U.S. border continues to increase as the rate of infestations in Mexico increases annually.

The regulations in "Subpart—Fruit Flies" (7 CFR 301.32 through 301.32–10, referred to below as the regulations), restrict the movement of certain regulated articles from quarantined areas in order to prevent the spread of fruit flies to noninfested areas of the United States. Within the quarantined areas, Animal and Plant Health Inspection Service (APHIS) works with State and local officials to eradicate fruit flies, after which the quarantine can be removed.

Current efforts to eradicate infestations include chemical and nonchemical control measures. Chemical options may include applications of insecticides and/or the use of detection and control attractants that can be applied using various methods. Nonchemical control methods include sterile insect technique (SIT) and host removal from areas in and around the detection sites.

Under the provisions of the National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C 4321 *et seq.*), Federal agencies must examine the potential environmental effects of the proposed Federal actions and alternatives. A final environmental impact statement (EIS) was prepared in 2001 to examine the environmental effects of the fruit fly cooperative control program. Since the publication of the 2001 EIS, there have been scientific and technological advances in the field. As a result, we are planning to prepare a new EIS to analyze and examine the environmental effects of control alternatives available to the agency, including a no action alternative. It will be used for planning and decisionmaking and to inform the public about the environmental effects of APHIS' fruit fly eradication activities. It will also provide an overview of APHIS activities to which we can tier site-specific analyses and environmental assessments if new fruit fly infestations are discovered in the United States.

We are requesting public comment to help us identify or confirm potential alternatives and environmental issues that should be examined in the EIS, as well as comments that identify other issues that should be examined in the EIS.

The EIS will be prepared in accordance with: (1) NEPA, (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

We have identified four alternatives for further examination in the EIS:

No action. Under this alternative, APHIS would maintain the program that was described in the 2001 EIS and Record of Decision. This alternative includes methods to exclude, detect, prevent, and control (both nonchemical and chemical) fruit fly infestations. This alternative represents the baseline against which a proposed action may be compared.

No eradication alternative. Under this alternative, APHIS would not control or cooperate with other governmental entities to eradicate exotic fruit flies. Any control efforts would be the responsibility of State and local governments, growers or grower groups, and individual citizens.

Quarantine and commodity treatment and certification. This alternative combines a Federal quarantine with commodity treatment and certification, as stipulated under the regulations. Regulated commodities harvested within the quarantined area would not be allowed to move unless treated with prescribed applications and certified for movement outside the area. Nonchemical treatment and host certification methods that may be used in this alternative include cold treatment, vapor heat treatment, and irradiation treatment. Regulatory certification chemical treatments may include fumigation with methyl bromide.

Integrated pest management approach. Under this alternative, APHIS would use methods to exclude, detect, prevent, and control fruit fly infestations. This alternative would update the information and technologies that were analyzed in the 2001 EIS. These methods could be used individually or in combination with other methods. In an integrated approach, program managers would make management decisions in such a way as to protect human health, nontarget species (endangered and threatened species), sensitive areas, and other components of the environment within the potential program area.

Program eradication efforts may employ any or a combination of the following: No action, regulatory quarantine treatment and control of host materials and regulated articles, host survey for evidence of breeding fruit flies, host removal, eradication chemical applications, mass trapping to delimit the infestation and monitor posttreatment populations, and use of SIT.

We have identified the following potential environmental impacts or issues for further examination in the EIS:

- Effects on wildlife, including consideration of migratory bird species and changes in native wildlife habitat and populations, and federally listed endangered and threatened species;
- Effects on soil, air, and water quality;
- Effects on human health and safety;
- Effects on cultural and historic resources; and
- Effects on economic resources.

We welcome comments on the proposed action, and on other alternatives and environmental impacts, or issues that should be considered for further examination in the EIS.

All comments on this notice will be carefully considered in developing the final scope of the EIS. Upon completion of the draft EIS, a notice announcing its availability and an invitation to comment on it will be published in the **Federal Register**.

Done in Washington, DC, this 8th day of August 2016.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2016–19223 Filed 8–11–16; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Forest Service

Flathead Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Flathead Resource Advisory Committee (RAC) will meet in Kalispell, Montana. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act. RAC information can be found at the following Web site: *http://www.fs.usda.gov/main/flathead/workingtogether/advisorycommittees.*

DATES: The meeting will be held on September 12, 2016, at 6:00 p.m.

All RAC meetings are subject to cancellation. For status of meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

ADDRESSES: The meeting will be held at Flathead National Forest Supervisor's Office, 650 Wolfpack Way, Kalispell, Montana.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION.** All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at the Flathead National Forest Supervisor's Office, 650 Wolfpack Way, Kalispell, Montana. Please call ahead at 406–758–5252 to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Janette Turk, Designated Federal Official by phone at 406–758–5252, or by email at *jturk@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to hear a presentation of project proposals for RAC consideration.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by September 7, 2016, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time to make oral comments must be sent to Janette Turk, Designated Federal Official, Flathead National Forest Supervisor's Office, 650 Wolfpack Way, Kalispell, Montana; or by email to *jturk@fs.fed.us,* or via facsimile to 406–758–5379.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices, or other reasonable accommodation. For access to the facility or proceedings, please contact the person listed in the section titled **FOR FURTHER INFORMATION**

CONTACT. All reasonable accommodation requests are managed on a case by case basis.

Dated: August 8, 2016.

Chip Weber,

Forest Supervisor.

[FR Doc. 2016–19225 Filed 8–11–16; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Southwest Mississippi Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Southwest Mississippi Resource Advisory Committee (RAC) will meet in Meadville, Mississippi. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act. RAC information can be found at the following Web site: *http://www.fs.usda.gov/main/r8/recreation/racs.*

DATE: The meeting will be held on September 15, 2016, at 6 p.m.

All RAC meetings are subject to cancellation. For status of meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

ADDRESSES: The meeting will be held at the Franklin County Public Library, 106 First Street, Meadville, Mississippi.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION.** All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at the Homochitto National Forest, 1200 Highway 184 East, Meadville, Mississippi. Please call ahead to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Bruce Prud'homme, Designated Federal Officer, by phone at 601–384–5876, ext.17 or via email at *bprudhomme@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to:

1. Welcome new members,
2. Nominate new chairperson,
3. Provide updates on the RAC (Information Sharing),
4. Discuss funding availability for projects, and
5. Discuss and recommend new projects.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by September 7, 2016, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time to make oral comments must be sent to Bill Meriwether, RAC Coordinator, 1200 Highway 184 East, Meadville, Mississippi 39653; or by email to *bdmeriwether@fs.fed.us,* or via facsimile to 601–384–2172.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices, or other reasonable accommodation. For access to the facility or proceedings, please contact the person listed in the section titled **FOR FURTHER INFORMATION CONTACT.** All reasonable accommodation requests are managed on a case by case basis.

Dated: August 1, 2016.

Bruce Prudhomme,

District Ranger.

[FR Doc. 2016–19160 Filed 8–11–16; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Flathead Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Flathead Resource Advisory Committee (RAC) will meet in Kalispell, Montana. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act. RAC information can be found at the following Web site: *http://www.fs.usda.gov/main/flathead/workingtogether/advisorycommittees.*

DATES: The meeting will be held on September 29, 2016, at 6:00 p.m.

All RAC meetings are subject to cancellation. For status of meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

ADDRESSES: The meeting will be held at the Flathead National Forest Supervisor's Office, 650 Wolfpack Way, Kalispell, Montana.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION**. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at the Flathead National Forest Supervisor's Office, 650 Wolfpack Way, Kalispell, Montana. Please call ahead at 406–758–5252 to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Janette Turk, Designated Federal Official by phone at 406–758–5252, or by email at *jturk@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to vote on funding project proposals.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by September 22, 2016, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time to make oral comments must be sent to Janette Turk, Designated Federal Official, Flathead National Forest Supervisor's Office, 650 Wolfpack Way, Kalispell, Montana 59901; or by email to *jturk@fs.fed.us,* or via facsimile to 406–758–5379.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices, or other reasonable accommodation. For access to the facility or proceedings, please contact the person listed in the section titled **FOR FURTHER INFORMATION CONTACT**. All reasonable accommodation requests are managed on a case by case basis.

Dated: August 8, 2016.

Chip Weber,

Forest Supervisor.

[FR Doc. 2016–19217 Filed 8–11–16; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Glenn and Colusa County Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Glenn and Colusa County Resource Advisory Committee (RAC) will meet in Willows, California. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act. RAC information can be found at the following Web site: *http://www.fs.usda.gov/main/pts/specialprojects/racweb.*

DATES: The meeting will be held on August 29, 2016, from 1:00 p.m. to 4:00 p.m.

All RAC meetings are subject to cancellation. For status of meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

ADDRESSES: The meeting will be held at the USDA Mendocino National Forest, Snow Mountain Conference Room, 825 North Humboldt Avenue, Willows, California.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION**. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at the USDA Mendocino National Forest, Grindstone Ranger District, 825 North Humboldt Avenue, Willows, California. Please call ahead at 530–934–3316 to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Zachary Rich, Committee Coordinator by phone at 530–934–1259, or via email at *zrich@fs.fed.us.* Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to discuss current or completed projects and present new projects for review. The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by August 22, 2016, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time for oral comments must be sent to Zachary Rich, Committee Coordinator, USDA Mendocino National Forest, Grindstone Ranger District, 825 North Humboldt Avenue, Willows, California 95988; or by email to *zrich@fs.fed,us,* or via facsimile to 530–934–7384.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices or other reasonable accommodation. For access to the facility or proceedings, please contact the person listed in the section titled **FOR FURTHER INFORMATION CONTACT**. All reasonable accommodation requests are managed on a case by case basis.

Dated: August 3, 2016.

Eduardo Olmedo,

District Ranger.

[FR Doc. 2016–18958 Filed 8–11–16; 8:45 am]

BILLING CODE 3411–15–M

DEPARTMENT OF AGRICULTURE

Forest Service

Flathead Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Flathead Resource Advisory Committee (RAC) will meet in Kalispell, Montana. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act. RAC information can be found at the following Web site: *http://www.fs.usda.gov/main/flathead/workingtogether/advisorycommittees.*

DATES: The meeting will be held on September 20, 2016, at 6:00 p.m.

All RAC meetings are subject to cancellation. For status of meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

ADDRESSES: The meeting will be held at the Flathead National Forest Supervisor's Office, 650 Wolfpack Way, Kalispell, Montana.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION**. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at the Flathead National Forest Supervisor's Office, 650 Wolfpack Way, Kalispell, Montana. Please call ahead at 406–758–5252 to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Janette Turk, Designated Federal Official by phone at 406–758–5252, or by email at *jturk@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to:

1. Hear presentation of project proposals for RAC consideration, and
2. Begin vetting projects for quorum vote.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by September 13, 2016, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time to make oral comments must be sent to Janette Turk, Designated Federal Official, Flathead National Forest Supervisor's Office, 650 Wolfpack Way, Kalispell, Montana 59901; or by email to *jturk@fs.fed.us,* or via facsimile to 406–758–5379.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices, or other reasonable accommodation. For access to the facility or proceedings, please contact the person listed in the section titled **FOR FURTHER INFORMATION CONTACT**. All reasonable accommodation requests are managed on a case by case basis.

Dated: August 20, 2016.

Chip Weber,

Forest Supervisor.

[FR Doc. 2016–19303 Filed 8–11–16; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

National Agricultural Statistics Service

Submission for OMB Review; Comment Request

August 9, 2016.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding (1) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by September 12, 2016 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725—17th Street NW., Washington, DC 20503. Commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@omb.eop.gov* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8681.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

National Agricultural Statistics Service

Title: Fruits, Nut, and Specialty Crops.

OMB Control Number: 0535–0039.

Summary of Collection: The primary function of the National Agricultural Statistics Service (NASS) is to prepare and issue current official state and national estimates of crop and livestock production. Estimates of fruit, tree nuts, and specialty crops are an integral part of this program. These estimates support the NASS strategic plan to cover all agricultural cash receipts. The authority to collect these data activities is granted under U.S. Code title 7, Section 2204(a). Information is collected on a voluntary basis from growers, processors, and handlers through surveys.

Need and Use of the Information: Data reported on fruit, nut, specialty crops and Hawaii tropical crops are used by NASS to estimate acreage, yield, production, price, utilization, and value of citrus and non-citrus fruits and nuts and other specialty crops in States with significant commercial production. These estimates are essential to farmers, processors, and handlers in making production and marketing decisions. Estimates from these inquiries are used by market order administrators in their determination of expected supplies of crop under federal and state market orders as well as competitive fruits and nuts.

Description of Respondents: Farms; Business or other for-profit.

Number of Respondents: 84,045.

Frequency of Responses: Reporting: On occasion; Annually; Quarterly; Semi-annually; Monthly.

Total Burden Hours: 36,816.

Charlene Parker,

Departmental Information Collection Clearance Officer.

[FR Doc. 2016–19218 Filed 8–11–16; 8:45 am]

BILLING CODE 3410–20–P

COMMISSION ON CIVIL RIGHTS

Sunshine Act Meeting Notice

AGENCY: United States Commission on Civil Rights.

ACTION: Notice of Commission Business Meeting.

DATES: Friday, August 19, 2016, at 10:00 a.m. EST.

ADDRESSES: National Place Building, 1331 Pennsylvania Ave. NW., 11th Floor, Suite 1150, Washington, DC 20245 (Entrance on F Street NW.).

FOR FURTHER INFORMATION CONTACT: Brian Walch, Communications and Public Engagement Director. Telephone: (202) 376–8371; TTY: (202) 376–8116; Email: *publicaffairs@usccr.gov.*

SUPPLEMENTARY INFORMATION: This business meeting is open to the public. If you would like to listen to the business meeting, please contact the above for the call-in information.

Hearing-impaired persons who will attend the briefing and require the services of a sign language interpreter should contact Juanda Smith at (202) 376–8105 or at *signlanguage@usccr.gov* at least seven business days before the scheduled date of the meeting.

Meeting Agenda

I. Approval of Agenda
II. Business Meeting
  A. Program Planning
  - Discussion and vote on Commission statement concerning recent settlement requiring Texas to issue birth certificates to U.S. citizen children of undocumented immigrants.
  - Discussion and vote on Commission statement commemorating the first Asian American Member of Congress, Dalip Singh Saund.
  - Discussion and vote on Commission statement concerning the 100th Anniversary of the first female elected to Congress.
  - Discussion and vote on Commission Press Release on USCCR Report on Peaceful Coexistence.
  - Discussion and vote on Commission Press Release on Selection of Women in Prison as topic for 2017 Statutory Enforcement report.
  - Discussion and vote on Commission statement concerning U.S. Supreme Court's decision in *G.G.* v. *Gloucester County School Board.*
  - Discussion and vote on a letter to the Department of Education and Department of Justice Re: The Oklahoma State Advisory Committee's Report "Civil Rights and the School-to-Prison Pipeline in Oklahoma."

B. State Advisory Committees
- Presentation by North Carolina State Advisory Committee (SAC) Chair Matty Lazo-Chadderton on Civil Rights and Environmental Justice in North Carolina.
- State Advisory Committee Appointments
- North Carolina
- Kansas
- District of Columbia
- Ohio

C. Management and Operations
- Discussion and Vote on Commission 2017 Business Meeting Calendar.
- Discussion on 2017 Commemoration of 60th Anniversary of USCCR.
- Staff Director's Report.

III. Adjourn Meeting

Dated: August 9, 2016.

Brian Walch,

Director of Communications & Public Engagement, U.S. Commission on Civil Rights.

[FR Doc. 2016–19311 Filed 8–10–16; 11:15 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

First Responder Network Authority

[Docket Number: 160728668–6668–01]

RIN 0660–XC028

Notice of Availability of a Draft Programmatic Environmental Impact Statement for the Central Region of the Nationwide Public Safety Broadband Network and Notice of Public Meetings

AGENCY: First Responder Network Authority, National Telecommunications and Information Administration, U.S. Department of Commerce.

ACTION: Announcement of availability of a draft programmatic environmental impact statement and of public meetings.

SUMMARY: The First Responder Network Authority (''FirstNet'') announces the availability of the Draft Programmatic Environmental Impact Statement for the Central Region (''Draft PEIS''). FirstNet also announces a series of public meetings to be held throughout the Central Region to receive comments on the Draft PEIS. The Draft PEIS evaluates the potential environmental impacts of the proposed nationwide public safety broadband network in the Central Region, composed of Colorado, Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Montana, Nebraska, North Dakota, Ohio, South Dakota, Utah, Wisconsin, and Wyoming.

DATES: Submit comments on the Draft PEIS for the Central Region on or before October 11, 2016. FirstNet will also hold public meetings in each of the 16 states. See **SUPPLMENTARY INFORMATION** section for meeting dates.

ADDRESSES: At any time during the public comment period, members of the public, public agencies, and other interested parties are encouraged to submit written comments, questions, and concerns about the project for FirstNet's consideration or to attend any of the public meetings. Written comments may be submitted electronically via *www.regulations.gov,* FIRSTNET–2016–0003, or by mail to Genevieve Walker, Director of Environmental Compliance, First Responder Network Authority, National Telecommunications and Information Administration, U.S. Department of Commerce, 12201 Sunrise Valley Drive, M/S 243, Reston, VA 20192. Comments received will be made a part of the public record and may be posted to FirstNet's Web site (*www.firstnet.gov*) without change. Comments should be machine readable and should not be copy-protected. All personally identifiable information (*e.g.,* name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information. The Draft PEIS is available for download from *www.regulations.gov,* FIRSTNET–2016–0003. A CD containing the electronic files of this document is also available at public libraries (see Chapter 24 of the Draft PEIS for the complete distribution list). See **SUPPLMENTARY INFORMATION** section for public meeting addresses.

FOR FURTHER INFORMATION CONTACT: For more information on the Draft PEIS, contact Genevieve Walker, Director of Environmental Compliance, First Responder Network Authority, National Telecommunications and Information Administration, U.S. Department of Commerce, 12201 Sunrise Valley Drive, M/S 243, Reston, VA 20192.

SUPPLEMENTARY INFORMATION:

Public Meetings

Attendees can obtain information regarding the project and/or submit a comment in person during public meetings. The meeting details are as follows:

Attendees can obtain information regarding the project and/or submit a comment in person during public meetings. The meeting details are as follows:

- Des Moines, Iowa: September 7, 2016, from 4 p.m. to 8 p.m., Hyatt Place Des Moines/Downtown, 418 6th Avenue, Des Moines, IA 50309.
- St. Paul, Minnesota: September 7, 2016, from 4 p.m. to 8 p.m., The Saint Paul Hotel, 350 Market Street, St. Paul, MN 55102.
- Indianapolis, Indiana: September 13, 2016, from 4 p.m. to 8 p.m., JW Marriott Indianapolis, 10 S West Street, Indianapolis, IN 46204.
- Jefferson City, Missouri: September 13, 2016, from 4 p.m. to 8 p.m., DoubleTree by Hilton Hotel Jefferson City, 422 Monroe Street, Jefferson City, MO 65101.
- Columbus, Ohio: September 14, 2016, from 4 p.m. to 8 p.m., Residence Inn Columbus Downtown, 36 E. Gay Street, Columbus, OH 43215.
- Topeka, Kansas: September 14, 2016, from 4 p.m. to 8 p.m., Capitol Plaza Hotel & Convention Center Topeka, 1717 SW Topeka Boulevard, Topeka, KS 66612.
- Lincoln, Nebraska: September 15, 2016, from 4 p.m. to 8 p.m., The Lincoln Marriott Cornhusker Hotel, 333 South 13th Street, Lincoln, NE 68508.
- Denver, Colorado: September 20, 2016, from 4 p.m. to 8 p.m., Sheraton Denver West Hotel, 360 Union Boulevard, Lakewood, CO 80228.
- Bismarck, North Dakota: September 20, 2016, from 4 p.m. to 8 p.m., Best Western Plus Ramkota Hotel, 800 South 3rd Street, Bismarck, ND 58504.
- Cheyenne, Wyoming: September 21, 2016, from 4 p.m. to 8 p.m., Fairfield Inn & Suites Cheyenne Southwest/Downtown Area, 1820 West Lincolnway, Cheyenne, WY 82001.
- Pierre, South Dakota: September 21, 2016, from 4 p.m. to 8 p.m., Pierre ClubHouse Hotel & Suites, 808 West Sioux Avenue, Pierre, SD 57501.
- Salt Lake City, Utah: September 27, 2016, from 4 p.m. to 8 p.m., Salt Lake Marriott Downtown at City Creek, 75 South West Temple, Salt Lake City, UT 84101.
- Madison, Wisconsin: September 27, 2016, from 4 p.m. to 8 p.m., DoubleTree by Hilton Hotel Madison, 525 West Johnson Street, Madison, WI 53703.
- Helena, Montana: September 29, 2016, from 4 p.m. to 8 p.m., Lewis & Clark Library—Helena Branch, 120 S Last Chance Gulch, Helena, MT 59601.
- Springfield, Illinois: September 29, 2016, from 4 p.m. to 8 p.m., Wyndham Springfield City Centre, 700 East Adams Street, Springfield, IL 62701.
- Lansing, Michigan: October 6, 2016, from 4 p.m. to 8 p.m., East Lansing Marriott at University Place, 300 M.A.C. Avenue, East Lansing, MI 48823.

Background

The Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96, Title VI, 126 Stat. 156 (codified at 47 U.S.C. 1401 *et seq.*)) (the "Act") created and authorized FirstNet to take all actions necessary to ensure the building, deployment, and operation of an interoperable, nationwide public safety broadband network ("NPSBN") based on a single, national network architecture. The Act meets a longstanding and critical national infrastructure need, to create a single, nationwide network that will, for the first time, allow police officers, fire fighters, emergency medical service professionals, and other public safety entities to effectively communicate with each other across agencies and jurisdictions. The NPSBN is intended to enhance the ability of the public safety community to perform more reliably, effectively, and safely; increase situational awareness during an emergency; and improve the ability of the public safety community to effectively engage in those critical activities.

The National Environmental Policy Act of 1969 (42 U.S.C. 4321–4347) ("NEPA") requires federal agencies to undertake an assessment of environmental effects of their proposed actions prior to making a final decision and implementing the action. NEPA requirements apply to any federal project, decision, or action that may have a significant impact on the quality of the human environment. NEPA also establishes the Council on Environmental Quality ("CEQ"), which issued regulations implementing the procedural provisions of NEPA (see 40 CFR parts 1500–1508). Among other considerations, CEQ regulations at 40 CFR 1508.28 recommend the use of *tiering* from a "broader environmental impact statement (such as a national program or policy statements) with subsequent narrower statements or environmental analysis (such as regional or basin wide statements or ultimately site-specific statements) incorporating by reference the general discussions and concentrating solely on the issues specific to the statement subsequently prepared."

Due to the geographic scope of FirstNet (all 50 states, the District of Columbia, and five territories) and the diversity of ecosystems potentially traversed by the project, FirstNet has elected to prepare five regional PEISs. The five PEISs were divided into the East, Central, West, South, and Non-Contiguous Regions. The Central Region consists of Colorado, Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Montana, Nebraska, North Dakota, Ohio, South Dakota, Utah, Wisconsin, and Wyoming. The Draft PEIS analyzes potential impacts of the deployment and operation of the NPSBN on the natural and human environment in the Central Region, in accordance with FirstNet's responsibilities under NEPA.

Next Steps

All comments received by the public and any interested stakeholders will be evaluated and considered by FirstNet during the preparation of the Final PEIS. Once a PEIS is completed and a Record of Decision (ROD) is signed, FirstNet will evaluate site-specific documentation, as network design is developed, to determine if the proposed project has been adequately evaluated in the PEIS or warrants a Categorical Exclusion, an Environmental Assessment, or an Environmental Impact Statement.

Dated: August 9, 2016.

Genevieve Walker,

Director of Environmental Compliance, First Responder Network Authority.

[FR Doc. 2016–19265 Filed 8–11–16; 8:45 am]

BILLING CODE 3510–TL–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–475–818]

Certain Pasta From Italy: Preliminary Results of Antidumping Duty Administrative Review; 2014–2015

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: In response to requests from interested parties, the Department of Commerce (the Department) is conducting an administrative review of the antidumping duty order on certain pasta (pasta) from Italy, covering the period July 1, 2014, through June 30, 2015. The initiation of the instant review covered 31 companies, and we have partially rescinded the review with respect to nine companies, as discussed below. Thus, this review covers two mandatory respondents, Industria Alimentare Colavita S.p.A. (Indalco) and Liguori Pastificio Dal 1820 (Liguori), and 19 non-selected companies. We preliminarily determine that Indalco and Liguori made sales of subject merchandise at less than normal value during the period of review (POR). Interested parties are invited to comment on these preliminary results.

DATES: Effective August 12, 2016.

FOR FURTHER INFORMATION CONTACT: Joy Zhang or George McMahon, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–1168 or (202) 482–1167, respectively.

Background

On September 2, 2015, the Department published a notice of initiation of an administrative review of the antidumping order on pasta from Italy.[1] On December 24, 2015, the Department rescinded the instant review, in part, with respect to La Molisana SpA., Pasta Lensi S.r.L., Pastificio Andalini S.p.A., Azienda Agricola Casina Rossa di De Laurentiis Nicola, Pastificio Bolognese of Angelo R. Dicuonzo, I Sapori dell'Arca S.r.l., La Romagna S.r.l., Ser.com.snc, and Vero Lucano S.r.l.[2]

As explained in the memorandum from the Acting Assistant Secretary for Enforcement and Compliance, the Department exercised its discretion to toll all administrative deadlines due to a closure of the Federal Government. As a result, the revised deadline for the preliminary results of this review was April 7, 2016.[3] On March 17, 2016, the Department extended the deadline for the preliminary results to August 5, 2016.

Scope of the Order

Imports covered by the order are shipments of certain non-egg dry pasta. The merchandise subject to review is currently classifiable under items 1901.90.90.95 and 1902.19.20 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise subject to the order is dispositive.[4]

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[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 80 FR 53106 (September 2, 2015) (*Initiation Notice*).

[2] *See Certain Pasta From Italy: Notice of Partial Rescission of Antidumping Duty Administrative Review,* 80 FR 80320 (December 24, 2015).

[3] *See* Memorandum to the Record from Ron Lorentzen, Acting Assistant Secretary for Enforcement & Compliance, regarding "Tolling of Administrative Deadlines As a Result of the Government Closure During Snowstorm 'Jonas,' " dated January 27, 2016. If the new deadline falls on a non-business day, in accordance with the Department's practice, the deadline will become the next business day.

[4] For a full description of the scope of the order, *see* the "Decision Memorandum for the Preliminary Results of Antidumping Duty Administrative Review: Certain Pasta From Italy; 2014–2015," from Christian Marsh, Deputy Assistant Secretary for

Methodology

The Department is conducting this review in accordance with section 751(a)(2) of the Tariff Act of 1930, as amended (the Act). Constructed export price or export price is calculated in accordance with section 772 of the Act. Normal value is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying our preliminary results, *see* Preliminary Decision Memorandum dated concurrently with this notice and hereby adopted by this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov* and is available to all parties in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly on the internet at *http://enforcement.trade.gov/frn/index.html.* The signed Preliminary Decision Memorandum and the electronic version of the Preliminary Decision Memorandum are identical in content.

Preliminary Results of the Review

As a result of this review, the Department calculated a weighted-average dumping margin of 2.14 percent for Indalco and 5.74 percent for Liguori for the period July 1, 2014, through June 30, 2015. Therefore, in accordance with section 735(c)(5)(A) of the Act, the Department assigned the weighted-average of these two calculated weighted-average dumping margins, 3.19 percent, to the 19 non-selected companies in these preliminary results, as referenced below.[5]

Producer and/or exporter	Weighted-average dumping margin (percent)
Industria Alimentare Colavita S.p.A. (Indalco)	2.14
Liguori Pastificio Dal 1820 (Liguori)[6]	5.74
Agritalia S.r.L. (Agritalia)	3.19
Atar S.r.L. (Atar)	3.19
Corticella Molini e Pastifici S.p.A. (Corticella)	3.19
Delverde Industrie Alimentari S.p.A. (Delverde)	3.19
Domenico Paone fu Erasmo S.p.A. (Domenico)	3.19
F. Divella S.p.A. (F. Divella)	3.19
La Fabbrica della Pasta di Gragnano S.a.s. di Antonio Moccia (La Fabbrica)	3.19
Molino e Pastificio Tomasello S.r.L. (Tomasello)	3.19
P.A.P SNC DI Pazienza G.B. & C. (P.A.P)	3.19
Pasta Zara S.p.A. (Pasta Zara)	3.19
Pastificio Carmine Russo S.p.A. (Carmine)	3.19
Pastificio DiMartino Gaetano & F. lli S.r.L. (DiMartino)	3.19
Pastificio Fabianelli S.p.A. (Fabianelli)	3.19
Pastificio Felicetti S.r.L. (Felicetti)	3.19
Pastificio Labor S.r.L. (Labor)	3.19
Pastificio Riscossa F. lli Mastromauro S.p.A. (AKA Pastificio Riscossa F. lli. Mastromauro S.r.L.) (Riscossa)	3.19
Poiatti S.p.A. (Poiatti)	3.19
Premiato Pastificio Afreltra S.r. L. (Premiato)	3.19
Rustichella d'Abruzzo S.p.A. (Rustichella)	3.19

Assessment Rate

Upon issuance of the final results, the Department shall determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review. If the weighted-average dumping margin for Indalco or Liguori is not zero or *de minimis* (*i.e.,* less than 0.5 percent), we will calculate importer-specific *ad valorem* antidumping duty assessment rates based on the ratio of the total amount of dumping calculated for the importer's examined sales to the total entered value of those same sales in accordance with 19 CFR 351.212(b)(1). We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review when the importer-specific assessment rate calculated in the final results of this review is not zero or *de minimis.* Where either the respondent's weighted-average dumping margin is zero or *de minimis,* or an importer-specific assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties. The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review where applicable.

In accordance with the Department's "automatic assessment" practice, for entries of subject merchandise during the POR produced by each respondent for which they did not know that their merchandise was destined for the United States, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.

We intend to issue instructions to CBP 15 days after publication of the final results of this review.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the notice of final results of administrative review for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication of the final results of this administrative review, as provided by section 751(a)(2) of the Act: (1) The cash deposit rate for respondents noted above will be the rate established in the final results of this administrative review; (2) for merchandise exported by producers or exporters not covered in this administrative review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding; (3) if the exporter is not a firm covered in this review, a prior review, or the original investigation, but the producer is, the cash deposit rate

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Antidumping and Countervailing Duty Operations, to Ronald Lorentzen, Acting Assistant Secretary for Enforcement and Compliance, dated concurrently with this notice (Preliminary Decision Memorandum).

[5] The rate applied to the non-selected companies is a weighted-average percentage margin calculated based on the publicly-ranged U.S. volumes of the two reviewed companies with an affirmative dumping margin, for the period July 1, 2014, through June 30, 2015. *See* Memorandum to the File titled, "Certain Pasta From Italy: Margin for Respondents Not Selected for Individual Examination," dated concurrently with this notice.

[6] The Department previously found that Liguori and PAM are affiliated and calculated a margin for the consolidated entity. *See, e.g., Notice of Preliminary Results And Partial Rescission Of Antidumping Duty Administrative Review And Intent To Revoke The Antidumping Duty Order In Part,* 66 FR 34414 (June 28, 2001) unchanged in *Notice of Final Results of Antidumping Duty Administrative Review, Partial Rescission of Antidumping Duty Administrative Review and Revocation of Antidumping Duty Order in Part: Certain Pasta From Italy,* 67 FR 300 (January 3, 2002). In the instant review, Liguori reported that PAM ceased its operations as of October 24, 2014, and that PAM did not make any sales of subject merchandise to the United States during the POR. *See* Liguori's Section A questionnaire response dated December 4, 2015 at 2. We intend to follow-up with Customs and Border Protection (CBP) concerning Liguori's statement subsequent to these preliminary results and to allow interested parties an opportunity to comment on any information received from CBP. Therefore, for purposes of these preliminary results, we have preliminarily assigned PAM the same rate as Liguori, rather than making a preliminary no shipments determination with respect to PAM.

will be the rate established for the most recently completed segment of this proceeding for the producer of the subject merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 15.45 percent, the all-others rate established in the antidumping investigation as modified by the section 129 determination.[7] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure and Public Comment

The Department will disclose to parties to this proceeding the calculations performed in reaching the preliminary results within five days of the date of publication of these preliminary results.[8] Pursuant to 19 CFR 351.309(c), interested parties may submit cases briefs not later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[9] Parties who submit comments are requested to submit: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities. All briefs must be filed electronically using ACCESS. An electronically filed document must be received successfully in its entirety by the Department's electronic records system, ACCESS.

Interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, using Enforcement and Compliance's ACCESS system within 30 days of publication of this notice.[10] Requests should contain the party's name, address, and telephone number, the number of participants, and a list of the issues to be discussed. If a request for a hearing is made, we will inform parties of the scheduled date for the hearing which will be held at the U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, at a time and location to be determined.[11] Parties should confirm by telephone the date, time, and location of the hearing.

Unless the deadline is extended pursuant to section 751(a)(2)(B)(iv) of the Act, the Department will issue the final results of this administrative review, including the results of our analysis of the issues raised by the parties in their case briefs, within 120 days after issuance of these preliminary results.

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and increase the subsequent assessment of the antidumping duties by the amount of antidumping duties reimbursed.

These preliminary results of review are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: August 5, 2016.

Ronald Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

1. Summary
2. Background
3. Scope of the Order
4. Discussion of Methodology
    - Date of Sale
    - Comparisons to Normal Value
    - Product Comparisons
    - Determination of Comparison Method
    - Results of the Differential Pricing (DP) Analysis
    - Export Price
    - Normal Value
    - A. Home Market Viability
    - B. Level of Trade
    - C. Sales to Affiliated Customers
    - D. Cost of Production Analysis
    - 1. Calculation of Cost of Production
    - 2. Test of Home Market Prices
    - 3. Results of the COP Test
    - E. Calculation of Normal Value Based on Comparison Market Prices
    - F. Price-to-CV Comparison
    - G. Constructed Value
    - Margins for Companies Not Selected for Individual Examination
    - Currency Conversion
5. Recommendation

[FR Doc. 2016–19129 Filed 8–11–16; 8:45 am]

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[7] *See Implementation of the Findings of the WTO Panel in US—Zeroing (EC): Notice of Determinations Under Section 129 of the Uruguay Round Agreements Act and Revocations and Partial Revocations of Certain Antidumping Duty Orders,* 72 FR 25261 (May 4, 2007).

[8] *See* 19 CFR 351.224(b).

[9] *See* 19 CFR 351.309(d).

[10] *See* 19 CFR 351.310(c).

[11] *See* 19 CFR 351.310.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–602–809]

Certain Hot-Rolled Steel Flat Products From Australia: Final Determination of Sales at Less Than Fair Value

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce determines that certain hot-rolled steel flat products from Australia are being, or are likely to be, sold in the United States at less than fair value. The period of investigation is July 1, 2014, through June 30, 2015. The final estimated weighted-average dumping margins are listed below in the "Final Determination" section of this notice.

DATES: Effective August 12, 2016.

FOR FURTHER INFORMATION CONTACT: Frances Veith, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–4295.

SUPPLEMENTARY INFORMATION:

Background

The Department of Commerce (the "Department") published the preliminary determination on March 22, 2016.[1] A summary of the events that occurred since the Department published the *Preliminary Determination,* as well as a full discussion of the issues raised by parties for this final determination, may be found in the final Issues and Decision Memorandum.[2]

Scope of the Investigation

The products covered by this investigation are certain hot-rolled steel flat products ("hot-rolled steel") from Australia. For a full description of the scope of this investigation, *see* the "Scope of the Investigation," in Appendix II of this notice.

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[1] *See Certain Hot-Rolled Steel Flat Products from Australia: Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination,* 81 FR 15241 (March 22, 2016) ("*Preliminary Determination*") and accompanying Preliminary Decision Memorandum.

[2] *See* Memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Ronald K. Lorentzen, Acting Assistant Secretary for Enforcement and Compliance, "Issues and Decision Memorandum for the Final Affirmative Determination in the Antidumping Duty Investigation of Certain Hot-Rolled Steel Flat Products from Australia," ("Issues and Decision Memorandum"), dated concurrently with this determination and hereby adopted by this notice.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties in this investigation are addressed in the Issues and Decision Memorandum, which is hereby adopted by this notice.[3] A list of the issues raised is attached to this notice as Appendix I. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System ("ACCESS"). ACCESS is available to registered users at *https://access.trade.gov* and it is available to all parties in the Central Records Unit, Room B–8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/*. The signed and electronic versions of the Final Issues and Decision Memorandum are identical in content.

Verification

As provided in section 782(i) of the Tariff Act of 1930, as amended ("the Act"), in April and May 2016, the Department verified the sales and cost data reported by the mandatory respondents BlueScope Steel Ltd. ("BlueScope"). We used standard verification procedures, including an examination of relevant accounting and production records, and original source documents provided by BlueScope.

Changes to the Margin Calculations Since the Preliminary Determination

Based on our analysis of comments received and our findings at verification, we made certain changes to the margin calculations for BlueScope. For a discussion of these changes, *see* the Issues and Decision Memorandum. We have also revised the all-others rate.

Single Entity Treatment

For the reasons set forth in the Preliminary Decision Memorandum and in accordance with 19 CFR 351.401(f) and the Department's practice, we are continuing to treat BlueScope Steel Ltd., BlueScope Steel (AIS) Pty Ltd., and BlueScope Steel Distribution Pty Ltd. as a single entity, BlueScope, for the purposes of this final determination.[4]

All-Others Rate

Consistent with sections 735(c)(1)(B)(i)(II) and 735(c)(5) of the Act, the Department also calculated an estimated all-others rate. Section 735(c)(5)(A) of the Act provides that the estimated all-others rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero and *de minimis* margins, and any margins determined entirely under section 776 of the Act. Where the rates for investigated companies are zero or *de minimis,* or based entirely on facts otherwise available, section 735(c)(5)(B) of the Act instructs the Department to establish an "all others" rate using "any reasonable method.

BlueScope is the only respondent for which the Department calculated a company-specific rate. Therefore, for purposes of determining the "all others" rate and pursuant to section 735(d)(5)(A) of the Act, we are using the dumping margin calculated for BlueScope, as referenced in the "Final Determination" section below.

Final Determination

The Department determines that the following weighted-average dumping margins exist:

Exporter/producer	Weighted-average dumping margin (percent)
BlueScope Steel Ltd., BlueScope Steel (AIS) Pty Ltd., and BlueScope Steel Distribution Pty Ltd	29.37
All Others	29.37

Disclosure

We intend to disclose to parties in this proceeding the calculations performed for this final determination within five days of the date of public announcement of our final determination, in accordance with 19 CFR 351.224(b).

Continuation of Suspension of Liquidation

In accordance with section 735(c)(1)(B) of the Act, we are directing U.S. Customs and Border Protection ("CBP") to continue to suspend liquidation of all entries of hot-rolled steel from Australia, as described in the Scope of the Investigation in Appendix II, entered, or withdrawn from warehouse, for consumption on or after March 22, 2016, the date of publication in the **Federal Register** of the affirmative *Preliminary Determination.*

International Trade Commission ("ITC") Notification

In accordance with section 735(d) of the Act, we are notifying the ITC of our affirmative final determination of sales at less than fair value ("LTFV"). Because the final determination in this proceeding is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports of hot-rolled steel from Australia no later than 45 days after our final determination. If the ITC determines that material injury or threat of material injury does not exist, the proceeding will be terminated and all cash deposits will be refunded. If the ITC determines that such injury does exist, the Department will issue an antidumping duty order directing CBP to assess, upon further instruction by the Department, antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation.

Notification Regarding Administrative Protective Orders ("APO")

This notice serves as a reminder to parties subject to APO of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a violation subject to sanction.

This determination is issued and published in accordance with sections 735(d) and 777(i)(1) of the Act, and 19 CFR 351.210(c).

Dated: August 4, 2016.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Final Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the Investigation
IV. Scope Comments
V. Changes Since the Preliminary Determination
VI. Discussion of the Methodology
VII. Discussion of the Issues
  Comment 1: U.S. Sales of Nonprime (Secondary) Merchandise
  Comment 2: U.S.—Freight Cap
  Comment 3: U.S.—Cost of Production Interest Expense Ratio

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[3] *See* Issues and Decision Memorandum.

[4] *See* "Affiliation And Collapsing" section of the Preliminary Decision Memorandum.

Comment 4: U.S.—Credit Expense for U.S. Sales in Channels 1 and 2
Comment 5: Home Market—Sales Adjustments
Comment 6: Home Market—Interest Expense Ratio
Comment 7: Home Market—Adverse Facts Available to Sales Data for BSD
Comment 8: Home Market—Early Payment Discounts
VIII. Negative Finding of Critical Circumstances
IX. Recommendation

Appendix II

Scope of the Investigation

The products covered by this investigation are certain hot-rolled, flat-rolled steel products, with or without patterns in relief, and whether or not annealed, painted, varnished, or coated with plastics or other non-metallic substances. The products covered do not include those that are clad, plated, or coated with metal. The products covered include coils that have a width or other lateral measurement ("width") of 12.7 mm or greater, regardless of thickness, and regardless of form of coil (*e.g.*, in successively superimposed layers, spirally oscillating, etc.). The products covered also include products not in coils (*e.g.*, in straight lengths) of a thickness of less than 4.75 mm and a width that is 12.7 mm or greater and that measures at least 10 times the thickness. The products described above may be rectangular, square, circular, or other shape and include products of either rectangular or non-rectangular cross-section where such cross-section is achieve subsequent to the rolling process, *i.e.*, products which have been "worked after rolling" (*e.g.*, products which have been beveled or rounded at the edges). For purposes of the width and thickness requirements referenced above:

(1) Where the nominal and actual measurements vary, a product is within the scope if application of either the nominal or actual measurement would place it within the scope based on the definitions set forth above unless the resulting measurement makes the product covered by the existing antidumping[5] or countervailing duty[6] orders on Certain Cut-To-Length Carbon-Quality Steel Plate Products From the Republic of Korea (A–580–836; C–580–837), and

(2) where the width and thickness vary for a specific product (*e.g.*, the thickness of certain products with non-rectangular cross-section, the width of certain products with non-rectangular shape, etc.), the measurement at its greatest width or thickness applies.

Steel products included in the scope of this investigation are products in which: (1) Iron predominates, by weight, over each of the other contained elements; (2) the carbon content is 2 percent or less, by weight; and (3) none of the elements listed below exceeds the quantity, by weight, respectively indicated:

- 2.50 percent of manganese, or
- 3.30 percent of silicon, or
- 1.50 percent of copper, or
- 1.50 percent of aluminum, or
- 1.25 percent of chromium, or
- 0.30 percent of cobalt, or
- 0.40 percent of lead, or
- 2.00 percent of nickel, or
- 0.30 percent of tungsten, or
- 0.80 percent of molybdenum, or
- 0.10 percent of niobium, or
- 0.30 percent of vanadium, or
- 0.30 percent of zirconium.

Unless specifically excluded, products are included in this scope regardless of levels of boron and titanium.

For example, specifically included in this scope are vacuum degassed, fully stabilized (commonly referred to as interstitial-free (IF)) steels, high strength low alloy (HSLA) steels, the substrate for motor lamination steels, Advanced High Strength Steels (AHSS), and Ultra High Strength Steels (UHSS). IF steels are recognized as low carbon steels with micro-alloying levels of elements such as titanium and/or niobium added to stabilize carbon and nitrogen elements. HSLA steels are recognized as steels with micro-alloying levels of elements such as chromium, copper, niobium, titanium, vanadium, and molybdenum. The substrate for motor lamination steels contains micro-alloying levels of elements such as silicon and aluminum. AHSS and UHSS are considered high tensile strength and high elongation steels, although AHSS and UHSS are covered whether or not they are high tensile strength or high elongation steels.

Subject merchandise includes hot-rolled steel that has been further processed in a third country, including but not limited to pickling, oiling, levelling, annealing, tempering, temper rolling, skin passing, painting, varnishing, trimming, cutting, punching, and/or slitting, or any other processing that would not otherwise remove the merchandise from the scope of the investigation if performed in the country of manufacture of the hot-rolled steel.

All products that meet the written physical description, and in which the chemistry quantities do not exceed any one of the noted element levels listed above, are within the scope of this investigation unless specifically excluded. The following products are outside of and/or specifically excluded from the scope of this investigation:

- Universal mill plates (*i.e.*, hot-rolled, flat-rolled products not in coils that have been rolled on four faces or in a closed box pass, of a width exceeding 150 mm but not exceeding 1250 mm, of a thickness not less than 4.0 mm, and without patterns in relief);
- Products that have been cold-rolled (cold-reduced) after hot-rolling;[7]
- Ball bearing steels;[8]
- Tool steels;[9] and
- Silico-manganese steels;[10]

The products subject to this investigation are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers: 7208.10.1500, 7208.10.3000, 7208.10.6000, 7208.25.3000, 7208.25.6000, 7208.26.0030, 7208.26.0060, 7208.27.0030, 7208.27.0060, 7208.36.0030, 7208.36.0060, 7208.37.0030, 7208.37.0060, 7208.38.0015, 7208.38.0030, 7208.38.0090, 7208.39.0015, 7208.39.0030, 7208.39.0090, 7208.40.6030, 7208.40.6060, 7208.53.0000, 7208.54.0000, 7208.90.0000, 7210.70.3000, 7211.14.0030, 7211.14.0090, 7211.19.1500, 7211.19.2000, 7211.19.3000, 7211.19.4500, 7211.19.6000, 7211.19.7530, 7211.19.7560, 7211.19.7590, 7225.11.0000, 7225.19.0000, 7225.30.3050, 7225.30.7000, 7225.40.7000, 7225.99.0090, 7226.11.1000, 7226.11.9030, 7226.11.9060, 7226.19.1000, 7226.19.9000, 7226.91.5000, 7226.91.7000, and 7226.91.8000. The products subject to the investigation may also enter under the following HTSUS numbers: 7210.90.9000, 7211.90.0000, 7212.40.1000, 7212.40.5000, 7212.50.0000, 7214.91.0015, 7214.91.0060, 7214.91.0090, 7214.99.0060, 7214.99.0075, 7214.99.0090, 7215.90.5000, 7226.99.0180, and 7228.60.6000.

The HTSUS subheadings above are provided for convenience and U.S. Customs purposes only. The written description of the scope of the investigation is dispositive.

[FR Doc. 2016–19375 Filed 8–11–16; 8:45 am]

BILLING CODE 3510–DS–P

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[5] *Notice of Amendment of Final Determinations of Sales at Less Than Fair Value and Antidumping Duty Orders: Certain Cut-To-Length Carbon-Quality Steel Plate Products From France, India, Indonesia, Italy, Japan and the Republic of Korea,* 65 FR 6585 (February 10, 2000).

[6] *Notice of Amended Final Determinations: Certain Cut-to-Length Carbon-Quality Steel Plate From India and the Republic of Korea; and Notice of Countervailing Duty Orders: Certain Cut-To-Length Carbon-Quality Steel Plate From France, India, Indonesia, Italy, and the Republic of Korea,* 65 FR 6587 (February 10, 2000).

[7] For purposes of this scope exclusion, rolling operations such as a skin pass, levelling, temper rolling or other minor rolling operations after the hot-rolling process for purposes of surface finish, flatness, shape control, or gauge control do not constitute cold-rolling sufficient to meet this exclusion.

[8] Ball bearing steels are defined as steels which contain, in addition to iron, each of the following elements by weight in the amount specified: (i) Not less than 0.95 nor more than 1.13 percent of carbon; (ii) not less than 0.22 nor more than 0.48 percent of manganese; (iii) none, or not more than 0.03 percent of sulfur; (iv) none, or not more than 0.03 percent of phosphorus; (v) not less than 0.18 nor more than 0.37 percent of silicon; (vi) not less than 1.25 nor more than 1.65 percent of chromium; (vii) none, or not more than 0.28 percent of nickel; (viii) none, or not more than 0.38 percent of copper; and (ix) none, or not more than 0.09 percent of molybdenum.

[9] Tool steels are defined as steels which contain the following combinations of elements in the quantity by weight respectively indicated: (i) More than 1.2 percent carbon and more than 10.5 percent chromium; or (ii) not less than 0.3 percent carbon and 1.25 percent or more but less than 10.5 percent chromium; or (iii) not less than 0.85 percent carbon and 1 percent to 1.8 percent, inclusive, manganese; or (iv) 0.9 percent to 1.2 percent, inclusive, chromium and 0.9 percent to 1.4 percent, inclusive, molybdenum; or (v) not less than 0.5 percent carbon and not less than 3.5 percent molybdenum; or (vi) not less than 0.5 percent carbon and not less than 5.5 percent tungsten.

[10] Silico-manganese steel is defined as steels containing by weight: (i) Not more than 0.7 percent of carbon; (ii) 0.5 percent or more but not more than 1.9 percent of manganese, and (iii) 0.6 percent or more but not more than 2.3 percent of silicon.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–588–874]

Certain Hot-Rolled Steel Flat Products From Japan: Final Determination of Sales at Less Than Fair Value and Final Affirmative Determination of Critical Circumstances

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) determines that certain hot-rolled steel flat products (hot-rolled steel) from Japan are being, or are likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is July 1, 2014, through June 30, 2015. The final dumping margins of sales at LTFV are listed below in the "Final Determination" section of this notice.

DATES: Effective August 12, 2016.

FOR FURTHER INFORMATION CONTACT: Myrna Lobo or Jun Jack Zhao, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–2371 or (202) 482–1396, respectively.

SUPPLEMENTARY INFORMATION:

Background

On March 22, 2016, the Department published the *Preliminary Determination* of this antidumping duty (AD) investigation.[1] A summary of the events that occurred since the Department published the *Preliminary Determination,* as well as a full discussion of the issues raised by parties for this final determination, may be found in the Final Issues and Decision Memorandum.[2]

Scope of the Investigation

The products covered by this investigation are hot-rolled steel flat products from Japan. For a full description of the scope of this investigation, *see* the "Scope of the Investigation," in Appendix I of this notice.

Scope Comments

In the Preliminary Scope Decision Memorandum,[3] the Department set aside a period of time for parties to address scope issues in case briefs or other written comments on scope issues.

In the *Preliminary Determination,* we did not modify the scope language as it appeared in the *Initiation Notice.*[4] No interested parties submitted scope comments, except for Nippon Steel & Sumitomo Metal Corporation/Nippon Steel & Sumikin Bussan Corporation (collectively, the Nippon Group) in its case brief and petitioner United States Steel Corporation in its rebuttal brief. These comments are addressed in the Final Issues and Decision Memorandum. The scope of this investigation remains unchanged for this final determination.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties in this investigation are addressed in the Final Issues and Decision Memorandum, which is hereby adopted by this notice.[5] A list of the issues raised is attached to this notice as Appendix II. The Final Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System ("ACCESS"). ACCESS is available to registered users at *https://access.trade.gov* and it is available to all parties in the Central Records Unit, Room B–8024 of the main Department of Commerce building. In addition, a complete version of the Final Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/index.html.* The signed and electronic versions of the Final Issues and Decision Memorandum are identical in content.

Verification

As provided in section 782(i) of the Tariff Act of 1930, as amended (the Act), in March, April, and May 2016, the Department verified the sales and cost data reported by the mandatory respondents and their affiliates Nippon Steel & Sumitomo Metal Corporation/Nippon Steel & Sumikin Bussan Corporation (collectively, the Nippon Group) and JFE Steel Corporation/JFE Shoji Trade Corporation (collectively, the JFE Group). We used standard verification procedures, including an examination of relevant accounting and production records, and original source documents provided by respondents.

Changes Since the Preliminary Determination

Based on our analysis of the comments received and our findings at verification, we made certain changes to the margin calculations for the Nippon Group and the JFE Group. For a discussion of these changes, *see* the Final Issues and Decision Memorandum. We have also revised the all-others rate consistent with the methodology described below.

All-Others Rate

Consistent with sections 735(c)(1)(B)(i)(II) and 735(c)(5) of the Act, the Department also calculated an estimated all-others rate. Section 735(c)(5)(A) of the Act provides that the estimated all-others rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero and *de minimis* margins, and any margins determined entirely under section 776 of the Act. We calculated weighted-average dumping margins for the Nippon Group and the JFE Group, that are above *de minimis* and which are not based on total facts available. Therefore, we calculated the all-others rate using a weighted-average of the dumping margins calculated for the mandatory respondents using each company's publicly-ranged values for the merchandise under consideration.[6]

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[1] *See Certain Hot-Rolled Steel Flat Products from Japan: Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination,* 81 FR 15222 (March 22, 2016) (*Preliminary Determination*) and accompanying Preliminary Decision Memorandum.

[2] *See* Memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Ronald K. Lorentzen, Acting Assistant Secretary for Enforcement and Compliance, "Issues and Decision Memorandum for the Final Affirmative Determination in the Antidumping Duty Investigation of Certain Hot-Rolled Steel Flat Products from Japan," (Final Issues and Decision Memorandum), dated concurrently with this determination and hereby adopted by this notice.

[3] *See* Memorandum to Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, "Certain Hot-Rolled Steel Products From Australia, Brazil, Japan, the Netherlands, the Republic of Korea, Turkey, and the United Kingdom: Scope Comments Decision Memorandum for the Preliminary Determinations" dated March 14, 2016 (Preliminary Scope Decision Memorandum).

[4] *See* Preliminary Decision Memorandum at page 5. *See also Certain Hot-Rolled Steel Flat Products From Australia, Brazil, Japan, the Republic of Korea, the Netherlands, The Republic of Turkey, and the United Kingdom: Initiation of Less-Than-Fair-Value Investigations,* 80 FR 54261, 54262 (September 9, 2015) (*Initiation Notice*).

[5] *See* Final Issues and Decision Memorandum.

[6] With two respondents, we would normally calculate (A) a weighted-average of the dumping margins calculated for the mandatory respondents; (B) a simple average of the dumping margins calculated for the mandatory respondents; and (C) a weighted-average of the dumping margins calculated for the mandatory respondents using each company's publicly-ranged values for the merchandise under consideration. We would compare (B) and (C) to (A) and select the rate closest

Continued

Final Determination

The Department determines that the final weighted-average dumping margins are as follows:

Exporter/producer	Weighted-average dumping margins (percent)
Nippon Steel & Sumitomo Metal Corporation/Nippon Steel & Sumikin Bussan Corporation	4.99
JFE Steel Corporation/JFE Shoji Trade Corporation	7.51
All-Others	5.58

Final Affirmative Determination of Critical Circumstances, in Part

Prior to the *Preliminary Determination,* the Department found that critical circumstances exist with respect to imports of hot-rolled steel from Japan produced or exported by the Nippon Group and the JFE Group and that critical circumstances did not exist with respect to all-other producers/exporters.[7] As discussed in the Final Issues and Decision Memorandum, in accordance with section 735(a)(3) of the Act, we no longer find critical circumstances with respect to the JFE Group, and we now find that critical circumstances exist with respect to all-other producers/exporters. We continue to find that critical circumstances exist with respect to the Nippon Group.[8]

Disclosure

We intend to disclose the calculations performed to interested parties within five days of the public announcement of this final determination in accordance with 19 CFR 351.224(b).

Continuation of Suspension of Liquidation

Pursuant to section 735(c)(1)(B) of the Act, the Department will instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of all entries of hot-rolled steel from Japan, which were entered, or withdrawn from warehouse, for consumption on or after December 23, 2015 (for those entities for which we found critical circumstances exist) or on or after March 22, 2016, the date of publication in the **Federal Register** of the affirmative *Preliminary Determination* (for all entities for which we did not find critical circumstances exist). Because we find in this final determination that critical circumstances exist for all-other producers/exporters, we will instruct CBP to suspend liquidation of all such entries on or after December 23, 2015 (which is 90 days prior to the publication of the *Preliminary Determination*) consistent with section 735(c)(4)(B) of the Act and require cash deposits. Further, because we find critical circumstances do not exist for the JFE Group, we will terminate the retroactive suspension of liquidation ordered at the *Preliminary Determination* and release any cash deposits that were required during that period, consistent with section 735(c)(3) of the Act.

Further, pursuant to section 735(c)(1)(B)(ii) of the Act, CBP shall require a cash deposit equal to the estimated amount by which the normal value exceeds the U.S. price, as follows: (1) For the exporter/producer listed in the table above, the cash deposit rate will be equal to the weighted average dumping margin which the Department determined in this final determination; (2) if the exporter is not a firm identified in this investigation but the producer is, the rate will be the rate established for the producer of the subject merchandise; (3) the rate for all other producers or exporters will be 5.58 percent, as discussed in the "All-Others Rate" section, above. These instructions suspending liquidation will remain in effect until further notice.

U.S. International Trade Commission Notification

In accordance with section 735(d) of the Act, we will notify the U.S. International Trade Commission (ITC) of the final affirmative determination of sales at LTFV. Because the final determination in this proceeding is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports of hot-rolled steel from Japan no later than 45 days after our final determination. If the ITC determines that material injury or threat of material injury does not exist, the proceeding will be terminated and all cash deposits will be refunded. If the ITC determines that such injury does exist, the Department will issue an antidumping duty order directing CBP to assess, upon further instruction by the Department, antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation, as discussed above in the "Continuation of Suspension of Liquidation" section.

Notification Regarding Administrative Protective Orders

This notice serves as a reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a violation subject to sanction.

This determination and this notice are issued and published pursuant to sections 735(d) and 777(i)(1) of the Act.

Dated: August 4, 2016.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix I—Scope of the Investigation

The products covered by this investigation are certain hot-rolled, flat-rolled steel products, with or without patterns in relief, and whether or not annealed, painted, varnished, or coated with plastics or other non-metallic substances. The products covered do not include those that are clad, plated, or coated with metal. The products covered include coils that have a width or other lateral measurement ("width") of 12.7 mm or greater, regardless of thickness, and regardless of form of coil (*e.g.,* in successively superimposed layers, spirally oscillating, etc.). The products covered also include products not in coils (*e.g.,* in straight lengths) of a thickness of less than 4.75 mm and a width that is 12.7 mm or greater and that measures at least 10 times the thickness. The products described above may be rectangular, square, circular, or other shape and include products of either rectangular or non-rectangular cross-section where such cross-section is achieve subsequent to the rolling process, *i.e.,* products which have been "worked after rolling" (*e.g.,* products which have been beveled or rounded at the edges). For purposes of the width and thickness requirements referenced above:

(1) Where the nominal and actual measurements vary, a product is within the scope if application of either the nominal or actual measurement would place it within the scope based on the definitions set forth above unless the resulting measurement makes the product covered by the existing

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to (A) as the most appropriate rate for all other companies. *See Ball Bearings and Parts Thereof From France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews, Final Results of Changed-Circumstances Review, and Revocation of an Order in Part,* 75 FR 53661, 53663 (September 1, 2010). *See* Memorandum to the File, "Hot-Rolled Steel Flat Products from Japan: Calculation of the Margin for All Others Rate for the Final Determination," dated August 4, 2016.

[7] *See Antidumping Duty Investigations of Certain Hot-Rolled Steel Flat Products From Australia, Brazil, Japan, and the Netherlands and Countervailing Duty Investigation of Certain Hot-Rolled Steel Flat Products from Brazil: Preliminary Determinations of Critical Circumstances,* 80 FR 76444 (December 9, 2015).

[8] For a full description of the methodology and results of our analysis, *see* the Final Issues and Decision Memorandum.

antidumping[9] or countervailing duty[10] orders on Certain Cut-To-Length Carbon-Quality Steel Plate Products From the Republic of Korea (A–580–836; C–580–837), and

(2) Where the width and thickness vary for a specific product (*e.g.*, the thickness of certain products with non-rectangular cross-section, the width of certain products with non-rectangular shape, etc.), the measurement at its greatest width or thickness applies.

Steel products included in the scope of this investigation are products in which: (1) Iron predominates, by weight, over each of the other contained elements; (2) the carbon content is 2 percent or less, by weight; and (3) none of the elements listed below exceeds the quantity, by weight, respectively indicated:

- 2.50 percent of manganese, or
- 3.30 percent of silicon, or
- 1.50 percent of copper, or
- 1.50 percent of aluminum, or
- 1.25 percent of chromium, or
- 0.30 percent of cobalt, or
- 0.40 percent of lead, or
- 2.00 percent of nickel, or
- 0.30 percent of tungsten, or
- 0.80 percent of molybdenum, or
- 0.10 percent of niobium, or
- 0.30 percent of vanadium, or
- 0.30 percent of zirconium.

Unless specifically excluded, products are included in this scope regardless of levels of boron and titanium.

For example, specifically included in this scope are vacuum degassed, fully stabilized (commonly referred to as interstitial-free (IF)) steels, high strength low alloy (HSLA) steels, the substrate for motor lamination steels, Advanced High Strength Steels (AHSS), and Ultra High Strength Steels (UHSS). IF steels are recognized as low carbon steels with micro-alloying levels of elements such as titanium and/or niobium added to stabilize carbon and nitrogen elements. HSLA steels are recognized as steels with micro-alloying levels of elements such as chromium, copper, niobium, titanium, vanadium, and molybdenum. The substrate for motor lamination steels contains micro-alloying levels of elements such as silicon and aluminum. AHSS and UHSS are considered high tensile strength and high elongation steels, although AHSS and UHSS are covered whether or not they are high tensile strength or high elongation steels.

Subject merchandise includes hot-rolled steel that has been further processed in a third country, including but not limited to pickling, oiling, levelling, annealing, tempering, temper rolling, skin passing, painting, varnishing, trimming, cutting, punching, and/or slitting, or any other processing that would not otherwise remove the merchandise from the scope of the investigation if performed in the country of manufacture of the hot-rolled steel.

All products that meet the written physical description, and in which the chemistry quantities do not exceed any one of the noted element levels listed above, are within the scope of this investigation unless specifically excluded. The following products are outside of and/or specifically excluded from the scope of this investigation:

- Universal mill plates (*i.e.*, hot-rolled, flat-rolled products not in coils that have been rolled on four faces or in a closed box pass, of a width exceeding 150 mm but not exceeding 1250 mm, of a thickness not less than 4.0 mm, and without patterns in relief);
- Products that have been cold-rolled (cold-reduced) after hot-rolling;[11]
- Ball bearing steels;[12]
- Tool steels;[13] and
- Silico-manganese steels;[14]

The products subject to this investigation are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers: 7208.10.1500, 7208.10.3000, 7208.10.6000, 7208.25.3000, 7208.25.6000, 7208.26.0030, 7208.26.0060, 7208.27.0030, 7208.27.0060, 7208.36.0030, 7208.36.0060, 7208.37.0030, 7208.37.0060, 7208.38.0015, 7208.38.0030, 7208.38.0090, 7208.39.0015, 7208.39.0030, 7208.39.0090, 7208.40.6030, 7208.40.6060, 7208.53.0000, 7208.54.0000, 7208.90.0000, 7210.70.3000, 7211.14.0030, 7211.14.0090, 7211.19.1500, 7211.19.2000, 7211.19.3000, 7211.19.4500, 7211.19.6000, 7211.19.7530, 7211.19.7560, 7211.19.7590, 7225.11.0000, 7225.19.0000, 7225.30.3050, 7225.30.7000, 7225.40.7000, 7225.99.0090, 7226.11.1000, 7226.11.9030, 7226.11.9060, 7226.19.1000, 7226.19.9000, 7226.91.5000, 7226.91.7000, and 7226.91.8000. The products subject to the investigation may also enter under the following HTSUS numbers: 7210.90.9000, 7211.90.0000, 7212.40.1000, 7212.40.5000, 7212.50.0000, 7214.91.0015, 7214.91.0060, 7214.91.0090, 7214.99.0060, 7214.99.0075, 7214.99.0090, 7215.90.5000, 7226.99.0180, and 7228.60.6000.

The HTSUS subheadings above are provided for convenience and U.S. Customs and Border Protection purposes only. The written description of the scope of the investigation is dispositive.

Appendix II—List of Topics Discussed in the Final Issues and Decision Memorandum

I. Summary
II. Background
III. Final Determination of Critical Circumstances, in Part
IV. Scope of the Investigation
V. Scope Comments
VI. Changes Since the Preliminary Determination
VII. Comparison to Fair Value
VIII. Discussion of the Issues
  Nippon Group
  Comment 1: Whether the Department Should Continue to Apply AFA to Steelscape's Sales of Non-prime Merchandise
  Comment 2: Whether the Department Should Continue to Apply AFA to Home Market Sales by Certain of Nippon Group's Affiliated Downstream Resellers.
  Comment 3: Whether the Department Should Include Freight Revenue and Fuel Revenue on U.S. Sales Made by Steelscape.
  Comment 4: Whether the Department Should Reduce the Weight of the Margin Calculated for Sales by One of the Nippon Group's CEP Resellers
  Comment 5: Whether the Department Should Accept the Destination Key for One of its CEP Resellers as a Minor Correction
  Comment 6: Whether the Department Should Apply AFA on Unreported Data and Whether the Department Should Decline to Increase the Cost of Further Manufacturing to Reflect its Calculation of a Markup that Steelscape Washington Charged to its Parent, Steelscape LLC, for Processing Services Performed by Steelscape Washington
  Comment 7: Whether the Department Should Find that Critical Circumstances Exist for Imports of the Merchandise Under Consideration Shipped by Nippon Group
  Comment 8: Whether the Department Should Revise its Differential Pricing Analysis
  Comment 9: Whether the Department Should Exclude Certain Products Produced by Nippon Group from the Scope of the Investigation

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[9] *See Notice of Amendment of Final Determinations of Sales at Less Than Fair Value and Antidumping Duty Orders: Certain Cut-To-Length Carbon-Quality Steel Plate Products From France, India, Indonesia, Italy, Japan and the Republic of Korea,* 65 FR 6585 (February 10, 2000).

[10] *See Notice of Amended Final Determinations: Certain Cut-to-Length Carbon-Quality Steel Plate From India and the Republic of Korea; and Notice of Countervailing Duty Orders: Certain Cut-To-Length Carbon-Quality Steel Plate From France, India, Indonesia, Italy, and the Republic of Korea,* 65 FR 6587 (February 10, 2000).

[11] For purposes of this scope exclusion, rolling operations such as a skin pass, levelling, temper rolling or other minor rolling operations after the hot-rolling process for purposes of surface finish, flatness, shape control, or gauge control do not constitute cold-rolling sufficient to meet this exclusion.

[12] Ball bearing steels are defined as steels which contain, in addition to iron, each of the following elements by weight in the amount specified: (i) Not less than 0.95 nor more than 1.13 percent of carbon; (ii) not less than 0.22 nor more than 0.48 percent of manganese; (iii) none, or not more than 0.03 percent of sulfur; (iv) none, or not more than 0.03 percent of phosphorus; (v) not less than 0.18 nor more than 0.37 percent of silicon; (vi) not less than 1.25 nor more than 1.65 percent of chromium; (vii) none, or not more than 0.28 percent of nickel; (viii) none, or not more than 0.38 percent of copper; and (ix) none, or not more than 0.09 percent of molybdenum.

[13] Tool steels are defined as steels which contain the following combinations of elements in the quantity by weight respectively indicated: (i) More than 1.2 percent carbon and more than 10.5 percent chromium; or (ii) not less than 0.3 percent carbon and 1.25 percent or more but less than 10.5 percent chromium; or (iii) not less than 0.85 percent carbon and 1 percent to 1.8 percent, inclusive, manganese; or (iv) 0.9 percent to 1.2 percent, inclusive, chromium and 0.9 percent to 1.4 percent, inclusive, molybdenum; or (v) not less than 0.5 percent carbon and not less than 3.5 percent molybdenum; or (vi) not less than 0.5 percent carbon and not less than 5.5 percent tungsten.

[14] Silico-manganese steel is defined as steels containing by weight: (i) Not more than 0.7 percent of carbon; (ii) 0.5 percent or more but not more than 1.9 percent of manganese, and (iii) 0.6 percent or more but not more than 2.3 percent of silicon.

Comment 10: Whether the Department Should Make an Adjustment for Nippon Group's Purchases of Iron Ore at Below Market Value
Comment 11: Whether the Department Should Accept Nippon Group's Value-Added Calculation and Its Unreported Further-Manufactured U.S. sales
Comment 12: Further Manufacturing Financial Expense Ratio
Comment 13: General & Administrative Expense Ratio
JFE Group
Comment 14: Whether the Department Erred in Applying Adverse Facts Available to Certain Downstream Home Market Sales
Comment 15: Whether Adverse Facts Available is Warranted for Other Unreported Downstream Sales
Comment 16: Whether Shoji America's Indirect Selling Expense Should be Increased
Comment 17: Whether Shoji America's Freight Expense Should be Increased
Comment 18: Whether Verification Minor Corrections Should be Incorporated into the Final Determination
Comment 19: Whether the Department Erred by Resetting JFES's Reported Home Market Credit Expense
Comment 20: Whether the Department Should Apply a CEP Offset on JFE's CEP Sales
Comment 21: Whether the Department Should Exclude Sales by CSI from its Antidumping Calculation
Comment 22: Whether the Department Should Continue to Apply AFA to the Cost of Inputs Supplied by JFE Shoji
Comment 23: Whether the Department Erred in Applying the Transactions Disregarded Adjustment
Comment 24: Whether the Department Should Adjust JFE's COM for Non-Prime Products
Comment 25: Whether the Department Should Increase JFE's COM for Reconciliation Differences
Tokyo Steel
Comment 26: Whether the Department's Refusal to Select Tokyo Steel as a Mandatory Respondent Is Unlawful
Comment 27: Whether the Department Should Correct the Clerical Error in Its Preliminary Results
IX. Recommendation

[FR Doc. 2016–19378 Filed 8–11–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–849]

Certain Cut-to-Length Carbon Steel Plate From the People's Republic of China: Preliminary Results of Antidumping Administrative Review, Preliminary Determination of No Shipments, in Part, and Partial Rescission; 2014–2015

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Effective August 12, 2016.

SUMMARY: The Department of Commerce ("Department") is conducting an administrative review of the antidumping duty order on certain cut-to-length carbon steel plate ("CTL plate") from the People's Republic of China ("PRC") covering the period of review ("POR") November 1, 2014, through October 31, 2015. We preliminarily find that of the two companies under review, one made no shipments of subject merchandise during the POR and the other company has not demonstrated its eligibility for separate rate status, and, thus, is part of the PRC-wide entity. Interested parties are invited to comment on these preliminary results.

FOR FURTHER INFORMATION CONTACT: Jonathan Hill, AD/CVD Operations, Office IV, Enforcement & Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–3518.

SUPPLEMENTARY INFORMATION:

Background

After initiating this review,[1] the Department issued an antidumping duty questionnaire to Hunan Valin Xiangtan Iron and Steel Co., Ltd. ("Hunan Valin"), which notified the Department that it would not respond to the questionnaire. The other respondent, Wuyang Iron & Steel Co., Ltd. ("Wuyang Steel") reported that it made no exports, sales, or entries during the POR. All review requests were timely withdrawn for the other 14 companies for which this review was initiated. For a complete description of the events that followed the initiation of this administrative review, see the Preliminary Decision Memorandum hereby adopted by, this notice.[2]

The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System ("ACCESS"). ACCESS is available to registered users at *http://access.trade.gov* and in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Results Decision Memorandum can be accessed directly on the Internet at *http://enforcement.trade.gov/frn/index.html.* The signed and the electronic versions of the Preliminary Decision Memorandum are identical in content.

The Department has exercised its discretion to toll all administrative deadlines due to the closure of the Federal Government because of Snowstorm "Jonas". Thus, all of the deadlines in this segment of the proceeding have been extended by four business days. The revised deadline for the preliminary results of review is now August 5, 2016.[3]

Scope of the Order

The product covered by the order is certain cut-to-length carbon steel plate from the PRC.[4] This merchandise is currently classified in the Harmonized Tariff Schedule of the United States ("HTSUS") under item numbers 7208.40.3030, 7208.40.3060, 7208.51.0030, 7208.51.0045, 7208.51.0060, 7208.52.0000, 7208.53.0000, 7208.90.0000, 7210.70.3000, 7212.40.5000, and 7212.50.0000. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the order is dispositive.

Partial Rescission

Pursuant to 19 CFR 351.213(d)(1), the Department will rescind an administrative review, in whole or in part, if a party that requested the review withdraws its request within 90 days of the date of publication of the notice of initiation of the requested review. Nucor Corporation ("Petitioner"), the only party to request a review of the companies listed below, withdrew its request for an administrative review of these 14 companies within 90 days of the date of publication of *Initiation Notice*.[5] Accordingly, the Department is rescinding this review, in part, with respect to the following companies, in accordance with 19 CFR 351.213(d)(1):[6]

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[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 81 FR 739 (January 7, 2016) ("*Initiation Notice*").

[2] *See* the memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations to Ronald K. Lorentzen, Acting Assistant Secretary for Enforcement and Compliance "Decision Memorandum for the Preliminary Results of the Antidumping Duty Administrative Review of Certain Cut-to-Length Carbon Steel Plate from the People's Republic of China," dated concurrently with this notice ("Preliminary Decision Memorandum").

[3] *See* Memorandum to the Record from Ron Lorentzen, Acting Assistant Secretary for Enforcement & Compliance, regarding "Tolling of Administrative Deadlines as a Result of the Government Closure during Snowstorm Jonas," dated January 27, 2016.

[4] For a complete description of the scope of the order *see* Preliminary Decision Memorandum.

Fujitrans Corporation
Guangzhou Metals and Minerals Imp. & Exp. Ltd.
Guardian Shanghai
Hong Kong Shengyu Trading Co. Ltd.
Hong Kong Zhong Yuan Industrial Co., Ltd.
Jiangyin Xingcheng Plastic Chemical Co., Ltd.
Jiangyin Xingcheng Special Steel Works Co., Ltd.
Ningbo Jiangdong Trusty Import and Export Co., Ltd.
Shanghai Ruyi Import and Export Co., Ltd.
Shanxi Taigang Stainless Steel Co., Ltd.
Shenzhen Wins Technology Co., Ltd.
UBI Logistics China Limited
Wuxi Philloy Machinery Co., Ltd.
Xiamen C&D Paper & Pulp Co., Ltd.

Methodology

The Department is conducting this review in accordance with section 751(a)(1)(B) of the Tariff Act of 1930, as amended ("the Act"). For a full discussion of the decisions taken in these preliminary results, *see* the Preliminary Decision Memorandum.

Preliminary Results of Review

As noted above, Hunan Valin did not respond to the Department's antidumping duty questionnaire. Therefore, the Department preliminarily determines that Hunan Valin has not demonstrated its eligibility for separate rate status and is part of the PRC-wide entity.[7] The PRC-wide entity rate is 128.59 percent.[8]

Preliminary Determination of No Shipments

Wuyang Steel submitted a timely-filed certification that it had no exports, sales, or entries of subject merchandise during the POR.[9] A query of U.S. Customs and Border Protection ("CBP") data did not show any POR entries of subject merchandise from Wuyang Steel.[10] In addition, CBP did not identify any entries of subject merchandise from Wuyang Steel during the POR in response to an inquiry from the Department asking CBP for such information.[11] Based on the foregoing, the Department preliminarily determines that Wuyang Steel did not have any reviewable transactions during the POR. For additional information regarding this determination, *see* the Preliminary Decision Memorandum.

Consistent with its practice in NME cases, the Department is not rescinding this administrative review for Wuyang Steel, but intends to complete the review and issue appropriate instructions to CBP based on the final results of the review.

Public Comment

Interested parties are invited to comment on the preliminary results and may submit case briefs and/or written comments, filed electronically using ACCESS, within 30 days of the date of publication of this notice, pursuant to 19 CFR 351.309(c)(1)(ii). Rebuttal briefs, limited to issues raised in the case briefs, will be due five days after the due date for case briefs, pursuant to 19 CFR 351.309(d). Parties who submit case or rebuttal briefs in this review are requested to submit with each argument a statement of the issue, a summary of the argument not to exceed five pages, and a table of statutes, regulations, and cases cited, in accordance with 19 CFR 351.309(c)(2).

Pursuant to 19 CFR 351.310(c), interested parties, who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, filed electronically using ACCESS. Electronically filed case briefs/written comments and hearing requests must be received successfully in their entirety by the Department's electronic records system, ACCESS, by 5:00 p.m. Eastern Time, within 30 days after the date of publication of this notice.[12] Hearing requests should contain: (1) The party's name, address and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those issues raised in the respective case briefs. If a request for a hearing is made, parties will be notified of the time and date of the hearing which will be held at the U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington DC 20230.

Unless extended, the Department intends to issue the final results of this administrative review, including the results of its analysis of the issues raised in any written briefs, not later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act.

Assessment Rates

Upon issuance of the final results of this review, the Department will determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review.[13] The Department intends to issue assessment instructions to CBP 15 days after the publication date of the final results of this review. The Department intends to instruct CBP to liquidate any entries of subject merchandise from Hunan Valin at 128.59 percent (the PRC-wide rate). Additionally, pursuant to the Department's practice in NME cases, if we continue to determine that Wuyang Steel had no shipments of subject merchandise, any suspended entries of subject merchandise during the POR from Wuyang Steel will be liquidated at the PRC-wide rate.[14]

For companies for which the review has been rescinded, the Department will instruct CBP to assess antidumping duties on entries of subject merchandise at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(l)(i).

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[5] *See* Letter from Petitioner to the Secretary of Commerce "*Certain Cut-To-Length Carbon Steel Plate from the People's Republic of China:* Withdrawal of Request for Administrative Review," dated April 6, 2016.

[6] As stated in *Change in Practice in NME Reviews*, the Department will no longer consider the non-market economy ("NME") entity as an exporter conditionally subject to administrative reviews. *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings*, 78 FR 65963 (November 4, 2013) ("*Change in Practice in NME Reviews*"). The PRC-wide entity is not subject to this administrative review because no interested party requested a review of the entity. *See Initiation Notice.*

[7] *See* Preliminary Decision Memorandum.

[8] *See Final Determination of Sales at Less Than Fair Value: Certain Cut-to-Length Carbon Steel Plate From the People's Republic of China*, 62 FR 61964 (November 20, 1997). Because no party requested a review of the PRC-wide entity in this segment of the proceeding, the entity's rate is not subject to change. *See Change in Practice in NME Reviews.*

[9] *See* Letter from Wuyang Steel to the Secretary of Commerce "*Administrative Review of Certain Cut-to-Length Carbon Steel Plate from China: Wuyang Iron & Steel's No Shipment Certification*," dated January 15, 2016.

[10] *See* letter from Howard Smith, Program Manager, AD/CVD Operations, Office IV, Enforcement & Compliance to interested parties dated January 21, 2016.

[11] *See* CBP Message Number 6155301 dated June 3, 2016.

[12] *See* 19 CFR 351.310(c).

[13] *See* 19 CFR 351.212(b)(1).

[14] For a full discussion of this practice, *see Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties*, 76 FR 65694 (October 24, 2011).

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of review, as provided by section 751(a)(2)(C) of the Act: (1) For previously investigated or reviewed PRC and non-PRC exporters which are not under review in this segment of the proceeding but which have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recent period; (2) for all PRC exporters of subject merchandise that have not been granted a separate rate, including Hunan Valin, the cash deposit rate will be the PRC-wide rate of 128.59 percent; and (3) for all non-PRC exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporter(s) that supplied that non-PRC exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Department's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213(d)(4) and 351.221(b)(4).

Dated: August 5, 2016.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix

List of Sections in the Preliminary Decision Memorandum

Summary
Background
Scope of the Order
Partial Rescission
Discussion of the Methodology
  Non-Market Economy Country Status
  Separate Rates
  Preliminary Determination of No Shipments
  Allegation of Duty Evasion
Recommendation

[FR Doc. 2016–19250 Filed 8–11–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–821–801]

Solid Urea From the Russian Federation: Preliminary Results of Antidumping Duty Administrative and New Shipper Reviews and Rescission of Administrative Review, in Part; 2014–2015

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) is conducting an administrative review and new shipper review of the antidumping duty order on solid urea from the Russian Federation (Russia). The period of review (POR) is July 1, 2014, through June 30, 2015. The Department preliminarily finds that MCC EuroChem and Joint Stock Company PhosAgro-Cherepovets (PhosAgro) have not made sales of subject merchandise in the United States at prices below normal value. Interested parties are invited to comment on these preliminary results.

DATES: Effective August 12, 2016.

FOR FURTHER INFORMATION CONTACT: Michael Romani or Andre Gziryan, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–0198 or (202) 482–2201, respectively.

SUPPLEMENTARY INFORMATION:

Scope of the Order

The merchandise subject to the order is solid urea, a high-nitrogen content fertilizer which is produced by reacting ammonia with carbon dioxide. The product is currently classified under the Harmonized Tariff Schedules of the United States (HTSUS) item number 3102.10.0010. Previously such merchandise was classified under item number 480.3000 and 3102.10.0000 of the HTSUS. Although the HTSUS subheading is provided for convenience and customs purposes, the written description of the merchandise subject to the order is dispositive.

Rescission of Administrative Review in Part

We are rescinding the administrative review in part with respect to PhosAgro.[1]

Methodology

The Department conducted these reviews in accordance with section 751(a)(2) of the Tariff Act of 1930, as amended (the Act). Export and constructed export price are calculated in accordance with section 772(a) and 772(b) of the Act respectively. Normal value is calculated in accordance with section 773(c) of the Act.

For a full description of the methodology underlying our conclusions, *see* Preliminary Decision Memorandum.[2] The Preliminary Decision Memorandum is a public document and is made available to the public *via* Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov*, and to all parties in the Central Records Unit, located at room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be found at *http://enforcement.trade.gov/frn/index.html*. A list of the topics discussed in the Preliminary Decision Memorandum is attached as an Appendix to this notice.

Preliminary Results of the Administrative Review

As a result of this administrative review, we preliminarily determine that a weighted-average dumping margin of 0.00 percent exists for MCC EuroChem[3] for the period July 1, 2014, through June 30, 2015.

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[1] *See* Preliminary Decision Memorandum at 3 for more details on this rescission in part. As noted in the Preliminary Decision Memorandum, we will not issue assessment instructions as a result of the rescission of the administrative review with respect to Phos Agro, given the ongoing new shipper review. *Id.* n.13.

[2] *See* memorandum from Gary Taverman, Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Ronald K. Lorentzen, Acting Assistant Secretary for Enforcement and Compliance, "Decision Memorandum for Preliminary Results of Antidumping Duty Administrative and New Shipper Review: Solid Urea from the Russian Federation," dated concurrently with this notice (Preliminary Decision Memorandum), which is hereby adopted by this notice.

[3] OJSC Nevinnomysskiy Azot, and OJSC NAK Azot (*a.k.a.*, Novomoskovskiy Azot, OJSC) are producing subsidiaries of MCC EuroChem.

Preliminary Results of the New Shipper Review

As a result of this new shipper review, we preliminarily determine that a weighted-average dumping margin of 0.00 percent exists for merchandise produced and exported by Joint Stock Company PhosAgro-Cherepovets for the period July 1, 2014, through June 30, 2015.

Disclosure and Public Comment

We intend to disclose the calculations performed for these preliminary results to the parties within five days after the date of publication of this notice.[4] Pursuant to 19 CFR 351.309(c), interested parties may submit cases briefs not later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in case briefs, may be filed no later than five days after the time limit for filing the case briefs.[5] Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[6]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. An electronically filed document must be received successfully in its entirety by the Department's electronic records system, ACCESS, by 5:00 p.m. Eastern Time within 30 days after the date of publication of this notice.[7] Requests should contain (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs.

Unless the deadline is extended pursuant to section 751(a)(2)(B)(iv) of the Act, the Department will issue the final results of these reviews, including the results of its analysis of issues raised by parties in their comments, within 120 days after the publication of these preliminary results, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h).

Assessment Rates

If a respondent's weighted-average dumping margin is above *de minimis* (*i.e.*, 0.50 percent) in the final results of these reviews, the Department will calculate an importer-specific assessment rate on the basis of the ratio of the total amount of dumping calculated for each importer's examined sales and, where possible, the total entered value of sales, in accordance with 19 CFR 351.212(b)(1).[8] If the respondent's weighted-average dumping margin continues to be zero or *de minimis* in the final results of review, we will instruct U.S. Customs and Border Protection (CBP) not to assess duties on any of its entries in accordance with the *Final Modification for Reviews*.[9]

For entries of subject merchandise during the POR produced by MCC EuroChem or PhosAgro for which it did not know its merchandise was destined for the United States, we will instruct CBP to liquidate unreviewed entries at the all-others rate of 64.93 percent[10] if there is no rate for the intermediate company(ies) involved in the transaction.

We intend to issue instructions to CBP 15 days after publication of the final results of these reviews.

Cash Deposit Requirements

The following deposit requirements will be effective upon publication of the notice of final results of these reviews for all shipments of solid urea from Russia entered, or withdrawn from warehouse, for consumption on or after the date of publication as provided by section 751(a)(2) of the Act: (1) The cash deposit rate with respect to the adminstrative review respondent, MCC EuroChem, will be the rate established in the final results of this administrative review; (2) for merchandise exported by manufacturers or exporters not covered in these reviews but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding; (3) if the exporter is not a firm covered in these reviews, a prior review, or the original investigation but the manufacturer is, the cash deposit rate will be the rate established for the manufacturer of the merchandise for the most recently completed segment of this proceeding; (4) the cash deposit rate for all other manufacturers or exporters will continue to be 64.93 percent.[11]

With respect to PhosAgro, the new shipper respondent, the Department established a combination cash deposit rate for this company consistent with its practice as follows: (1) For subject merchandise produced and exported by PhosAgro, the cash deposit rate will be the rate established for PhosAgro in the final results of the new shipper review; (2) for subject merchandise exported by PhosAgro, but not produced by PhosAgro, the cash deposit rate will be the rate for the all-others established in the less-than-fair-value investigation; and (3) for subject merchandise produced by PhosAgro but not exported by PhosAgro, the cash deposit rate will be the rate applicable to the exporter.

These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

We are issuing and publishing the preliminary results of these reviews in accordance with sections 751(a)(1), 751(a)(2)(B) and 777(i) of the Act and 19 CFR 351.213, 351.214 and 351.221(b)(4).

Dated: August 5, 2016.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Preliminary Decision Memorandum

Summary
Background
Rescission of Administrative Review in Part
Bona Fides Analysis
Comparisons to Normal Value
  A. Determination of Comparison Method
  B. Results of the Differential Pricing Analysis
Date of Sale
Product Comparisons
Export Price and Constructed Export Price
Normal Value
  A. Selection of Comparison Market
  B. Affiliated Party Transactions and Arm's-Length Test
  C. Level of Trade
  D. Cost of Production Analysis
  E. Calculation of Normal Value Based on Comparison Market Prices

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[4] *See* 19 CFR 351.224(b).

[5] *See* 19 CFR 351.309(d).

[6] *See* 19 CFR 351.310(c).

[7] *See* 19 CFR 351.310(c).

[8] In these preliminary results, the Department applied the assessment rate calculation method adopted in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Duty Proceedings; Final Modification*, 77 FR 8101 (February 14, 2012) (*Final Modification for Reviews*).

[9] *See Final Modification for Reviews*, 77 FR at 8102.

[10] The all-others rate established in *Urea From the Union of Soviet Socialist Republics; Final Determination of Sales at Less Than Fair Value*, 52 FR 19557 (May 26, 1987).

[11] *Id.*

Currency Conversion
Recommendation

[FR Doc. 2016–19261 Filed 8–11–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–351–846]

Countervailing Duty Investigation of Certain Hot-Rolled Steel Flat Products From Brazil: Final Affirmative Determination, and Final Determination of Critical Circumstances, in Part

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) determines that countervailable subsidies are being provided to producers and exporters of certain hot-rolled steel flat products (hot-rolled steel, or HRS) from Brazil. For information on the estimated subsidy rates, *see* the "Final Determination" section of this notice. The period of investigation is January 1, 2014, through December 31, 2014.

DATES: Effective August 12, 2016.

FOR FURTHER INFORMATION CONTACT: Sergio Balbontin, Nicholas Czajkowski, or Lana Nigro, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–6478, (202) 482–1395, and (202) 482–1779, respectively.

SUPPLEMENTARY INFORMATION:

Background

The Department published the *Preliminary Determination* on January 15, 2016.[1] A summary of the events that occurred since the Department published the *Preliminary Determination,* as well as a full discussion of the issues raised by parties for this final determination, may be found in the Issues and Decision Memorandum.[2] The Issues and Decision Memorandum is a public document and is on file electronically *via* Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov,* and is available to all parties in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed Issues and Decision Memorandum and the electronic version are identical in content.

Scope Comments

In accordance with the Preliminary Scope Determination,[3] the Department set aside a period of time for parties to address scope issues in case briefs or other written comments on scope issues.

In the *Preliminary Determination,* we did not modify the scope language as it appeared in the *Initiation Notice.*[4] No interested party submitted scope comments in case or rebuttal briefs; therefore, the scope of this investigation remains unchanged for this final determination.

Scope of the Investigation

The products covered by this investigation are certain hot-rolled steel flat products from Brazil. For a complete description of the scope of this investigation, *see* the "Scope of the Investigation," attached to this notice at Appendix I.

Analysis of Subsidy Programs and Comments Received

The subsidy programs under investigation and the issues raised in the case and rebuttal briefs by parties in this investigation are discussed in the Issues and Decision Memorandum. A list of the issues that parties raised, and to which we have responded in the Issues and Decision Memorandum, is attached to this notice at Appendix II.

Use of Adverse Facts Available

In making this final determination, the Department relied, in part, on facts available and, because the Government of Brazil and the respondent companies did not act to the best of their abilities in responding to the Department's requests for information, we drew an adverse inference where appropriate in selecting from among the facts otherwise available.[5] Specifically, we applied facts available, with adverse inferences, for the Reduction of Tax on Industrialized Products for Machines and Equipment, the BNDES FINAME Loan program, and the Ex-Tarifário program, in accordance with section 776(a) and (b) of the Act. For further information, *see* the section "Use of Adverse Facts Available" in the accompanying Issues and Decision Memorandum.

Changes Since the Preliminary Determination

Based on our analysis of the comments received from parties, and the minor corrections presented and additional items discovered at verification, we made certain changes to the respondents' subsidy rate calculations. For a discussion of these changes, *see* the Issues and Decision Memorandum.

Final Affirmative Determination of Critical Circumstances, in Part

On October 23, 2015, the petitioner filed a timely critical circumstances allegation pursuant to section 703(e)(1) of the Act and 19 CFR 351.206(c)(1), alleging that critical circumstances exist with respect to imports of hot-rolled steel from Brazil.[6] We preliminarily determined that critical circumstances existed with respect to CSN and Usiminas, but not for all others companies.[7] Based on additional import data that became available since the *Preliminary Determination of Critical Circumstances,* we are departing from our preliminary finding. For this final determination, in accordance with section 705(a) of the Act, we find that critical circumstances exist with respect to CSN but that critical circumstances do not exist with respect to Usiminas and all other producers and exporters of hot-rolled steel from Brazil.[8] For a complete discussion, *see* the "Critical Circumstances" section of the Issues and Decision Memorandum.

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[1] *See Countervailing Duty Investigation of Certain Hot-Rolled Steel Flat Products From Brazil: Preliminary Affirmative Determination and Alignment of Final Determination With Final Antidumping Duty Determination,* 81 FR 2168 (January 15, 2016) (*Preliminary Determination*) and accompanying Preliminary Decision Memorandum (PDM).

[2] *See* Memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Ronald K. Lorentzen, Acting Assistant Secretary for Enforcement and Compliance, "Issues and Decision Memorandum for the Final Determination in the Countervailing Duty Investigation of Certain Hot-Rolled Steel Flat Products from Brazil," dated concurrently with this determination (Issues and Decision Memorandum) and hereby adopted by this notice.

[3] *See* Memorandum to Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, "Certain Hot-Rolled Steel Products from Australia, Brazil, Japan, the Netherlands, the Republic of Korea, Turkey and the United Kingdom: Scope Comments Decision Memorandum for the Preliminary Determinations," dated March 14, 2016.

[4] *See Preliminary Determination* PDM at "Scope Comments."

[5] *See* sections 776(a) and (b) of the Tariff Act of 1930, as amended (the Act).

[6] *See* letter from the Petitioner, "Certain Hot-Rolled Steel Flat Products From Australia, Brazil, Japan and the Netherlands—Critical Circumstances Allegations," dated October 23, 2015.

[7] *See Antidumping Duty Investigations of Certain Hot-Rolled Steel Flat Products From Australia, Brazil, Japan, and the Netherlands and Countervailing Duty Investigation of Certain Hot-Rolled Steel Flat Products From Brazil: Preliminary Determinations of Critical Circumstances,* 80 FR 76444 (December 9, 2015) (*Preliminary Determination of Critical Circumstances*).

Final Determination

In accordance with section 705(c)(1)(B)(i) of the Act, we calculated a rate for Usiminas and CSN, the exporters/producers of subject merchandise selected for individual examination in this investigation.

In accordance with sections 705(c)(1)(B)(i)(I) and 705(c)(5)(A) of the Act, for companies not individually investigated, we apply an "all others" rate, which is normally calculated by weighting the subsidy rates of the individual companies selected as mandatory respondents by those companies' exports of the subject merchandise to the United States. Under section 705(c)(5)(A)(i) of the Act, the all-others rate excludes zero and *de minimis* rates calculated for the exporters and producers individually investigated as well as any rates based entirely on facts otherwise available, pursuant to section 776 of the Act. Neither of the respondents' rates was zero or *de minimis* or based entirely on facts otherwise available. Notwithstanding the language of section 705(c)(5)(A)(i) of the Act, we did not calculate the "all-others" rate by weight averaging the rates of the two individually investigated respondents using their actual export sales data, because doing so risks disclosure of proprietary information. Instead, we calculated the all-others rate using the simple average of the respondents' calculated rates.[9] The estimated countervailable subsidy rates are as follows:

Company	Subsidy rate (percent)
Companhia Siderurgica Nacional (CSN)	11.30
Usinas Siderurgicas de Minas Gerais S.A. (Usiminas)	11.09
All Others	11.20

Suspension of Liquidation

As a result of our *Preliminary Determination* and pursuant to section 703(d) of the Act, we instructed U.S. Customs and Border Protection (CBP) to suspend liquidation of all entries of hot-rolled steel from Brazil, that were entered, or withdrawn from warehouse, for consumption on or after October 17, 2015, for CSN and Usiminas, for which we found critical circumstances exist, and on or after January 15, 2016, the date of the publication of the *Preliminary Determination* in the **Federal Register,** for all other exporters. In accordance with section 703(d) of the Act, we instructed CBP to discontinue the suspension of liquidation for countervailing duty (CVD) purposes for subject merchandise entered, or withdrawn from warehouse, on or after May 14, 2016, but to continue the suspension of liquidation of all entries from October 17, 2015, or January 15, 2016, as applicable, through May 14, 2016. As a result of our negative critical circumstances determination for Usiminas, we will instruct CBP to discontinue the suspension of liquidation, and to liquidate, without regard to countervailing duties, subject merchandise exported by Usiminas and entered, or withdrawn from warehouse, on or after October 17, 2015 and before January 15, 2016.

If the U.S. International Trade Commission (ITC) issues a final affirmative injury determination, we will issue a CVD order and will reinstate the suspension of liquidation under section 706(a) of the Act and will require a cash deposit of estimated CVDs for such entries of subject merchandise in the amounts indicated above. If the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated and all estimated duties deposited or securities posted as a result of the suspension of liquidation will be refunded or canceled.

ITC Notification

In accordance with section 705(d) of the Act, we will notify the ITC of our determination. In addition, we are making available to the ITC all non-privileged and non-proprietary information related to this investigation. We will allow the ITC access to all privileged and business proprietary information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under an administrative protective order (APO), without the written consent of the Assistant Secretary for Enforcement and Compliance.

Notification Regarding Administrative Protective Orders

In the event that the ITC issues a final negative injury determination, this notice will serve as the only reminder to parties subject to an APO of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

This determination is issued and published pursuant to sections 705(d) and 777(i) of the Act and 19 CFR 351.201(c).

Dated: August 4, 2016.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix I—Scope of the Investigation

The products covered by this investigation are certain hot-rolled, flat-rolled steel products, with or without patterns in relief, and whether or not annealed, painted, varnished, or coated with plastics or other non-metallic substances. The products covered do not include those that are clad, plated, or coated with metal. The products covered include coils that have a width or other lateral measurement ("width") of 12.7 mm or greater, regardless of thickness, and regardless of form of coil (*e.g.*, in successively superimposed layers, spirally oscillating, etc.). The products covered also include products not in coils (*e.g.*, in straight lengths) of a thickness of less than 4.75 mm and a width that is 12.7 mm or greater and that measures at least 10 times the thickness. The products described above may be rectangular, square, circular, or other shape and include products of either rectangular or non-rectangular cross-section where such cross-section is achieve subsequent to the rolling process, *i.e.*, products which have been "worked after rolling" (*e.g.*, products which have been beveled or rounded at the edges). For purposes of the width and thickness requirements referenced above:

(1) Where the nominal and actual measurements vary, a product is within the scope if application of either the nominal or actual measurement would place it within the scope based on the definitions set forth above unless the resulting measurement makes the product covered by the existing antidumping[1] or countervailing duty[2] orders

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[8] *See* Issues and Decision Memorandum; *see also* Memorandum "Calculations for Final Determination of Critical Circumstances in the Countervailing Duty Investigation of Certain Hot-Rolled Steel Flat Products from Brazil," dated concurrently with this notice.

[9] *See* Memorandum to Dana S. Mermelstein, Program Manager, AD/CVD Operations, Office I, "Final Affirmative Countervailing Duty Determination: Hot-Rolled Steel Flat Products from Brazil; Calculation of the All Others Rate for the Final Determination in the Countervailing Duty Investigation of Hot-Rolled Steel Flat Products from Brazil," dated concurrently with this notice.

[1] *Notice of Amendment of Final Determinations of Sales at Less Than Fair Value and Antidumping Duty Orders: Certain Cut-To-Length Carbon-Quality Steel Plate Products From France, India, Indonesia, Italy, Japan and the Republic of Korea,* 65 FR 6585 (February 10, 2000).

[2] *Notice of Amended Final Determinations: Certain Cut-to-Length Carbon-Quality Steel Plate*

Continued

on Certain Cut-To-Length Carbon-Quality Steel Plate Products From the Republic of Korea (A–580–836; C–580–837), and

(2) Where the width and thickness vary for a specific product (*e.g.*, the thickness of certain products with non-rectangular cross-section, the width of certain products with non-rectangular shape, etc.), the measurement at its greatest width or thickness applies.

Steel products included in the scope of this investigation are products in which: (1) Iron predominates, by weight, over each of the other contained elements; (2) the carbon content is 2 percent or less, by weight; and (3) none of the elements listed below exceeds the quantity, by weight, respectively indicated:

- 2.50 percent of manganese, or
- 3.30 percent of silicon, or
- 1.50 percent of copper, or
- 1.50 percent of aluminum, or
- 1.25 percent of chromium, or
- 0.30 percent of cobalt, or
- 0.40 percent of lead, or
- 2.00 percent of nickel, or
- 0.30 percent of tungsten, or
- 0.80 percent of molybdenum, or
- 0.10 percent of niobium, or
- 0.30 percent of vanadium, or
- 0.30 percent of zirconium.

Unless specifically excluded, products are included in this scope regardless of levels of boron and titanium.

For example, specifically included in this scope are vacuum degassed, fully stabilized (commonly referred to as interstitial-free (IF)) steels, high strength low alloy (HSLA) steels, the substrate for motor lamination steels, Advanced High Strength Steels (AHSS), and Ultra High Strength Steels (UHSS). IF steels are recognized as low carbon steels with micro-alloying levels of elements such as titanium and/or niobium added to stabilize carbon and nitrogen elements. HSLA steels are recognized as steels with micro-alloying levels of elements such as chromium, copper, niobium, titanium, vanadium, and molybdenum. The substrate for motor lamination steels contains micro-alloying levels of elements such as silicon and aluminum. AHSS and UHSS are considered high tensile strength and high elongation steels, although AHSS and UHSS are covered whether or not they are high tensile strength or high elongation steels.

Subject merchandise includes hot-rolled steel that has been further processed in a third country, including but not limited to pickling, oiling, levelling, annealing, tempering, temper rolling, skin passing, painting, varnishing, trimming, cutting, punching, and/or slitting, or any other processing that would not otherwise remove the merchandise from the scope of the investigation if performed in the country of manufacture of the hot-rolled steel.

All products that meet the written physical description, and in which the chemistry quantities do not exceed any one of the noted element levels listed above, are within the scope of this investigation unless specifically excluded. The following products are outside of and/or specifically excluded from the scope of this investigation:

- Universal mill plates (*i.e.*, hot-rolled, flat-rolled products not in coils that have been rolled on four faces or in a closed box pass, of a width exceeding 150 mm but not exceeding 1250 mm, of a thickness not less than 4.0 mm, and without patterns in relief);
- Products that have been cold-rolled (cold-reduced) after hot-rolling; [3]
- Ball bearing steels; [4]
- Tool steels; [5] and
- Silico-manganese steels; [6]

The products subject to this investigation are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers: 7208.10.1500, 7208.10.3000, 7208.10.6000, 7208.25.3000, 7208.25.6000, 7208.26.0030, 7208.26.0060, 7208.27.0030, 7208.27.0060, 7208.36.0030, 7208.36.0060, 7208.37.0030, 7208.37.0060, 7208.38.0015, 7208.38.0030, 7208.38.0090, 7208.39.0015, 7208.39.0030, 7208.39.0090, 7208.40.6030, 7208.40.6060, 7208.53.0000, 7208.54.0000, 7208.90.0000, 7210.70.3000, 7211.14.0030, 7211.14.0090, 7211.19.1500, 7211.19.2000, 7211.19.3000, 7211.19.4500, 7211.19.6000, 7211.19.7530, 7211.19.7560, 7211.19.7590, 7225.11.0000, 7225.19.0000, 7225.30.3050, 7225.30.7000, 7225.40.7000, 7225.99.0090, 7226.11.1000, 7226.11.9030, 7226.11.9060, 7226.19.1000, 7226.19.9000, 7226.91.5000, 7226.91.7000, and 7226.91.8000. The products subject to the investigation may also enter under the following HTSUS numbers: 7210.90.9000, 7211.90.0000, 7212.40.1000, 7212.40.5000, 7212.50.0000, 7214.91.0015, 7214.91.0060, 7214.91.0090, 7214.99.0060, 7214.99.0075, 7214.99.0090, 7215.90.5000, 7226.99.0180, and 7228.60.6000.

The HTSUS subheadings above are provided for convenience and U.S. Customs purposes only. The written description of the scope of the investigation is dispositive.

Appendix II—List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
  - Issues
- II. Background
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  - B. Period of Investigation
- III. Final Determination of Critical Circumstances, in Part
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- V. Use of Adverse Facts Available
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  - C. Programs Determined To Be Not Used, or Not To Confer a Measurable Benefit, During the POI
  - D. Program Determined Not To Exist
- IX. Analysis of Comments
  - Comment 1: Whether To Apply AFA to Both the GOB and Respondents for the Reduction of IPI for Machines and Equipment Program
  - Comment 2: Whether the Reduction of IPI for Machines and Equipment Program Is Countervailable
  - Comment 3: Whether To Apply AFA for the Ex-Tarifário Program
  - Comment 4: Whether Ex-Tarifário is *De Facto* Specific
  - Comment 5: Whether Ex-Tarifário Provides a Financial Contribution
  - Comment 6: Whether the FINAME Loan Program Is Specific
  - Comment 7: Whether To Apply AFA to Determine the Benefit of the FINAME Program
  - Comment 8: Whether To Re-Calculate the FINAME Program for Usiminas
  - Comment 9: Whether To Use a Company-Specific Interest Rate Benchmark To Calculate the FINAME Program Benefit for Usiminas
  - Comment 10: Whether the Integrated Drawback Scheme Is Countervailable
  - Comment 11: Whether Usiminas Received a Benefit From the Integrated Drawback Scheme
  - Comment 12: Whether Reintegra Is Countervailable
  - Comment 13: Whether to Recalculate the Reintegra Subsidy Rate
  - Comment 14: Whether CSN Applied for/Used the Reintegra Program During the POI
  - Comment 15: Whether the Exemption of Payroll Tax Is Countervailable

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From India and the Republic of Korea; and Notice of Countervailing Duty Orders: Certain Cut-To-Length Carbon-Quality Steel Plate From France, India, Indonesia, Italy, and the Republic of Korea, 65 FR 6587 (February 10, 2000).

[3] For purposes of this scope exclusion, rolling operations such as a skin pass, levelling, temper rolling or other minor rolling operations after the hot-rolling process for purposes of surface finish, flatness, shape control, or gauge control do not constitute cold-rolling sufficient to meet this exclusion.

[4] Ball bearing steels are defined as steels which contain, in addition to iron, each of the following elements by weight in the amount specified: (i) Not less than 0.95 nor more than 1.13 percent of carbon; (ii) not less than 0.22 nor more than 0.48 percent of manganese; (iii) none, or not more than 0.03 percent of sulfur; (iv) none, or not more than 0.03 percent of phosphorus; (v) not less than 0.18 nor more than 0.37 percent of silicon; (vi) not less than 1.25 nor more than 1.65 percent of chromium; (vii) none, or not more than 0.28 percent of nickel; (viii) none, or not more than 0.38 percent of copper; and (ix) none, or not more than 0.09 percent of molybdenum.

[5] Tool steels are defined as steels which contain the following combinations of elements in the quantity by weight respectively indicated: (i) More than 1.2 percent carbon and more than 10.5 percent chromium; or (ii) not less than 0.3 percent carbon and 1.25 percent or more but less than 10.5 percent chromium; or (iii) not less than 0.85 percent carbon and 1 percent to 1.8 percent, inclusive, manganese; or (iv) 0.9 percent to 1.2 percent, inclusive, chromium and 0.9 percent to 1.4 percent, inclusive, molybdenum; or (v) not less than 0.5 percent carbon and not less than 3.5 percent molybdenum; or (vi) not less than 0.5 percent carbon and not less than 5.5 percent tungsten.

[6] Silico-manganese steel is defined as steels containing by weight: (i) Not more than 0.7 percent of carbon; (ii) 0.5 percent or more but not more than 1.9 percent of manganese, and (iii) 0.6 percent or more but not more than 2.3 percent of silicon.

Comment 16: Whether Subsidies Provided to UMSA Should Be Attributed to Usiminas
Comment 17: Whether the Economic Subvention to National Innovation Program Is Not Countervailable
Comment 18: Whether FINEP's Economic Subvention Program Has Not Conferred a Measurable Benefit
Comment 19: Whether the Bahia State Industrial Development and Economic Integration Program (Desenvolve) Is *De Jure* Specific
Comment 20: Whether the GOB's References to Web sites Constitute a Full Response
X. Recommendation

[FR Doc. 2016–19376 Filed 8–11–16; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–883]

Certain Hot-Rolled Steel Flat Products From the Republic of Korea: Final Determination of Sales at Less Than Fair Value

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Department) determines that certain hot-rolled steel flat products (hot-rolled steel) from the Republic of Korea (Korea) are being, or are likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is July 1, 2014, through June 30, 2015. The final estimated weighted-average dumping margins are listed below in the "Final Determination" section of this notice.

DATES: Effective August 12, 2016.

FOR FURTHER INFORMATION CONTACT: Javier Barrientos or Matthew Renkey, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–2243 or (202) 482–2312, respectively.

SUPPLEMENTARY INFORMATION:

Background

The Department published the preliminary determination on March 22, 2016.[1] A summary of the events that occurred since the Department published the *Preliminary Determination*, as well as a full discussion of the issues raised by parties for this final determination, may be found in the Final Issues and Decision Memorandum.[2]

Also, as explained in the memorandum from the Acting Assistant Secretary for Enforcement and Compliance, the Department exercised its authority to toll all administrative deadlines due to the closure of the Federal Government.[3] As a consequence, all deadlines in this segment of the proceeding have been extended by four business days.

Scope of the Investigation

The products covered by this investigation are certain hot-rolled steel flat products from Korea. For a complete description of the scope of this investigation, *see* the "Scope of the Investigation," in Appendix II of this notice.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties in this investigation are addressed in the Final Issues and Decision Memorandum, which is hereby adopted by this notice.[4] A list of the issues raised is attached to this notice as Appendix I. The Final Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov* and it is available to all parties in the Central Records Unit, room B–8024 of the main Department of Commerce building. In addition, a complete version of the Final Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/index.html.* The signed and electronic versions of the Final Issues and Decision Memorandum are identical in content.

Verification

As provided in section 782(i) of the Act, in January, April, and June 2016, the Department verified the sales, cost, and further manufacturing data reported by the mandatory respondents Hyundai Steel Company and POSCO,[5] pursuant to section 782(i) of the Act. We used standard verification procedures, including an examination of relevant accounting and production records, and original source documents provided by respondents.

Use of Adverse Facts Available

In making this final determination, the Department relied, in part, on facts available for both POSCO and Hyundai Steel Company. Furthermore, because Hyundai Steel Company did not act to the best of its ability in responding to certain of the Department's requests for information, we drew an adverse inference where appropriate in selecting from among the facts otherwise available.[6] For further information, *see* the accompanying Final Issues and Decision Memorandum.

Changes to the Margin Calculations Since the Preliminary Determination

Based on our analysis of the comments received and our findings at verification, we made certain changes to the margin calculations for Hyundai Steel Company and POSCO. For a discussion of these changes, *see* the Final Issues and Decision Memorandum. We have also revised the all-others rate in accordance with the methodology described below.

All-Others Rate

Consistent with sections 735(c)(1)(B)(i)(II) and 735(c)(5) of the Act, the Department also calculated an estimated all-others rate. Section 735(c)(5)(A) of the Act provides that the estimated all-others rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero and *de minimis* margins, and any margins determined entirely under section 776 of the Act. Where the rates for investigated companies are zero or *de minimis,* or based entirely on facts otherwise available, section 735(c)(5)(B) of the Act instructs the Department to establish an "all others" rate using "any reasonable method."

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[1] *See Certain Hot-Rolled Steel Flat Products from the Republic of Korea: Affirmative Preliminary Determination of Sales at Less than Fair Value and Postponement of Final Determination,* 81 FR 15228 (March 22, 2016) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum.

[2] *See* Memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Ronald K. Lorentzen, Acting Assistant Secretary for Enforcement and Compliance, "Issues and Decision Memorandum for the Final Affirmative Determination in the Antidumping Duty Investigation of Certain Hot-Rolled Steel Flat Products from the Republic of Korea," (Final Issues and Decision Memorandum), dated concurrently with this determination and hereby adopted by this notice.

[3] *See* Memorandum to the File from Ron Lorentzen, Acting A/S for Enforcement & Compliance, "Tolling of Administrative Deadlines As a Result of the Government Closure During Snowstorm Jonas," dated January 27, 2016.

[4] *See* Final Issues and Decision Memorandum.

[5] We are continuing to collapse the mandatory respondent POSCO and Daewoo International Corporation (DWI), and henceforward refer to the collapsed entity as "POSCO." *See Preliminary Determination,* 81 FR at 15229.

[6] *See* sections 776(a) and (b) of the Act.

In this investigation, we calculated weighted-average dumping margins for Hyundai Steel Company and POSCO that are above *de minimis* and which are not based on total facts available. Accordingly, for the final determination, consistent with the Act and the Department's practice, the Department calculated the margin for the all-others rate using the ranged total sales values reported by POSCO and Hyundai Steel from the public versions of their submissions.[7]

Final Determination Margins

The Department determines that the following estimated weighted-average dumping margins exist:

Exporter/Manufacturer	Weighted-average dumping margins (percent)	Cash deposit rate (percent)
Hyundai Steel Company	9.49	9.49
POSCO	3.89	0.00
All Others	5.55	5.55

Disclosure

We intend to disclose to parties in this proceeding the calculations performed for this final determination within five days of the date of public announcement of our final determination, in accordance with 19 CFR 351.224(b).

Continuation of Suspension of Liquidation

Pursuant to section 735(c)(1)(B) of the Act, the Department will instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of all entries of hot-rolled steel from Korea, which were entered, or withdrawn from warehouse, for consumption on or after March 22, 2016 (the date of publication of the affirmative *Preliminary Determination*).

Where the product under investigation is also subject to a concurrent countervailing duty investigation, we instruct CBP to require a cash deposit less the amount of the countervailing duty determined to constitute any export subsidies. Because of the affirmative final determination in the countervailing duty investigation, suspension of liquidation will be ordered in that investigation, and so long as suspension of liquidation continues under this antidumping duty investigation, the cash deposit rates for this antidumping duty investigation will be the rates identified in the cash deposit rate column in the rate chart, above. In the event that a countervailing duty order is issued and suspension of liquidation continues in the companion countervailing duty investigation on hot-rolled steel from the Korea, the Department will continue to instruct CBP to require cash deposits adjusted by the amount of export subsidies, as appropriate. These adjustments are reflected in the final column of the rate chart, above.

International Trade Commission Notification

In accordance with section 735(d) of the Act, we will notify the U.S. International Trade Commission (ITC) of the final affirmative determination of sales at LTFV. Because the final determination in this proceeding is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports of hot-rolled steel from Korea no later than 45 days after our final determination. If the ITC determines that material injury or threat of material injury does not exist, the proceeding will be terminated and all cash deposits will be refunded. If the ITC determines that such injury does exist, the Department will issue an antidumping duty order directing CBP to assess, upon further instruction by the Department, antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation.

Notification Regarding Administrative Protective Orders (APOs)

This notice serves as a reminder to parties subject to APO of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a violation subject to sanction.

This determination and notice are issued and published pursuant to sections 735(d) and 777(i)(1) of the Act.

Dated: August 4, 2016.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix I—List of Topics Discussed in the Final Issues and Decision Memorandum

I. Summary
II. Background
III. Period of Investigation
IV. Scope Comments
V. Scope of the Investigation
VI. Changes Since the Preliminary Determination
VII. Discussion of the Issues
  Company-Specific Comments
  POSCO
  1. Correction of Errors in the Margin Calculation
  2. The Correct Code for Prime Merchandise to Use in the Margin Calculation
  3. CEP Offset
  4. Treatment of Side-Trimming Costs Accepted as a Minor Correction
  5. Foreign Brokerage and Handling Expense for Channel 5 Sales
  6. Revision of Further Manufacturing Costs for Non-Prime Channel 5 Sales
  7. Date of Sale
  Hyundai Steel
  8. Reporting of Inland Freight, International Freight, Marine Insurance and Other Services Provided by Affiliated Companies
  9. CEP Offset
  10. Date of Sale
  11. Differential Pricing
  12. Hyundai Steel Calculation Issues
  13. Certain Home Market Customers
  14. Hyundai Steel America Channel 5 Issues
  15. Affiliated Home Market Resales

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[7] *See* Memorandum to the File, "Investigation of Certain Hot-Rolled Steel Flat Products from the Republic of Korea, All-Others Rate Calculation," dated August 4, 2016. We note that it is the Department's practice to calculate (A) a weighted-average of the dumping margins calculated for the mandatory respondents; (B) a simple average of the dumping margins calculated for the mandatory respondents; and (C) a weighted-average of the dumping margins calculated for the mandatory respondents using each company's publicly-ranged values for the merchandise under consideration. We would compare (B) and (C) to (A) and select the rate closest to (A) as the most appropriate rate for all other companies. *See Ball Bearings and Parts Thereof From France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews, Final Results of Changed-Circumstances Review, and Revocation of an Order in Part,* 75 FR 53661, 53663 (September 1, 2010).

VIII. Recommendation

Appendix II—Scope of the Investigation

The products covered by this investigation are certain hot-rolled, flat-rolled steel products, with or without patterns in relief, and whether or not annealed, painted, varnished, or coated with plastics or other non-metallic substances. The products covered do not include those that are clad, plated, or coated with metal. The products covered include coils that have a width or other lateral measurement (width) of 12.7 mm or greater, regardless of thickness, and regardless of form of coil (*e.g.,* in successively superimposed layers, spirally oscillating, *etc.*). The products covered also include products not in coils (*e.g.,* in straight lengths) of a thickness of less than 4.75 mm and a width that is 12.7 mm or greater and that measures at least 10 times the thickness. The products described above may be rectangular, square, circular, or other shape and include products of either rectangular or non-rectangular cross-section where such cross-section is achieve subsequent to the rolling process, *i.e.,* products which have been "worked after rolling" (*e.g.,* products which have been beveled or rounded at the edges). For purposes of the width and thickness requirements referenced above:

(1) Where the nominal and actual measurements vary, a product is within the scope if application of either the nominal or actual measurement would place it within the scope based on the definitions set forth above unless the resulting measurement makes the product covered by the existing antidumping[8] or countervailing duty[9] orders on Certain Cut-To-Length Carbon-Quality Steel Plate Products From the Republic of Korea (A–580–836; C–580–837), and

(2) where the width and thickness vary for a specific product (*e.g.,* the thickness of certain products with non-rectangular cross-section, the width of certain products with non-rectangular shape, etc.), the measurement at its greatest width or thickness applies.

Steel products included in the scope of this investigation are products in which: (1) Iron predominates, by weight, over each of the other contained elements; (2) the carbon content is 2 percent or less, by weight; and (3) none of the elements listed below exceeds the quantity, by weight, respectively indicated:

- 2.50 percent of manganese, or
- 3.30 percent of silicon, or
- 1.50 percent of copper, or
- 1.50 percent of aluminum, or
- 1.25 percent of chromium, or
- 0.30 percent of cobalt, or
- 0.40 percent of lead, or
- 2.00 percent of nickel, or
- 0.30 percent of tungsten, or
- 0.80 percent of molybdenum, or
- 0.10 percent of niobium, or
- 0.30 percent of vanadium, or
- 0.30 percent of zirconium.

Unless specifically excluded, products are included in this scope regardless of levels of boron and titanium.

For example, specifically included in this scope are vacuum degassed, fully stabilized (commonly referred to as interstitial-free (IF)) steels, high strength low alloy (HSLA) steels, the substrate for motor lamination steels, Advanced High Strength Steels (AHSS), and Ultra High Strength Steels (UHSS). IF steels are recognized as low carbon steels with micro-alloying levels of elements such as titanium and/or niobium added to stabilize carbon and nitrogen elements. HSLA steels are recognized as steels with micro-alloying levels of elements such as chromium, copper, niobium, titanium, vanadium, and molybdenum. The substrate for motor lamination steels contains micro-alloying levels of elements such as silicon and aluminum. AHSS and UHSS are considered high tensile strength and high elongation steels, although AHSS and UHSS are covered whether or not they are high tensile strength or high elongation steels.

Subject merchandise includes hot-rolled steel that has been further processed in a third country, including but not limited to pickling, oiling, levelling, annealing, tempering, temper rolling, skin passing, painting, varnishing, trimming, cutting, punching, and/or slitting, or any other processing that would not otherwise remove the merchandise from the scope of the investigation if performed in the country of manufacture of the hot-rolled steel.

All products that meet the written physical description, and in which the chemistry quantities do not exceed any one of the noted element levels listed above, are within the scope of this investigation unless specifically excluded. The following products are outside of and/or specifically excluded from the scope of this investigation:

- Universal mill plates (*i.e.,* hot-rolled, flat-rolled products not in coils that have been rolled on four faces or in a closed box pass, of a width exceeding 150 mm but not exceeding 1250 mm, of a thickness not less than 4.0 mm, and without patterns in relief);
- Products that have been cold-rolled (cold-reduced) after hot-rolling;[10]
- Ball bearing steels;[11]
- Tool steels;[12] and
- Silico-manganese steels;[13]

The products subject to this investigation are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers: 7208.10.1500, 7208.10.3000, 7208.10.6000, 7208.25.3000, 7208.25.6000, 7208.26.0030, 7208.26.0060, 7208.27.0030, 7208.27.0060, 7208.36.0030, 7208.36.0060, 7208.37.0030, 7208.37.0060, 7208.38.0015, 7208.38.0030, 7208.38.0090, 7208.39.0015, 7208.39.0030, 7208.39.0090, 7208.40.6030, 7208.40.6060, 7208.53.0000, 7208.54.0000, 7208.90.0000, 7210.70.3000, 7211.14.0030, 7211.14.0090, 7211.19.1500, 7211.19.2000, 7211.19.3000, 7211.19.4500, 7211.19.6000, 7211.19.7530, 7211.19.7560, 7211.19.7590, 7225.11.0000, 7225.19.0000, 7225.30.3050, 7225.30.7000, 7225.40.7000, 7225.99.0090, 7226.11.1000, 7226.11.9030, 7226.11.9060, 7226.19.1000, 7226.19.9000, 7226.91.5000, 7226.91.7000, and 7226.91.8000. The products subject to the investigation may also enter under the following HTSUS numbers: 7210.90.9000, 7211.90.0000, 7212.40.1000, 7212.40.5000, 7212.50.0000, 7214.91.0015, 7214.91.0060, 7214.91.0090, 7214.99.0060, 7214.99.0075, 7214.99.0090, 7215.90.5000, 7226.99.0180, and 7228.60.6000.

The HTSUS subheadings above are provided for convenience and U.S. Customs purposes only. The written description of the scope of the investigation is dispositive.

[FR Doc. 2016–19380 Filed 8–11–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

[International Trade Administration [A–421–813]

Certain Hot-Rolled Steel Flat Products From the Netherlands: Final Determination of Sales at Less Than Fair Value and Negative Final Determination of Critical Circumstances

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

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[8] *Notice of Amendment of Final Determinations of Sales at Less Than Fair Value and Antidumping Duty Orders: Certain Cut-To-Length Carbon-Quality Steel Plate Products From France, India, Indonesia, Italy, Japan and the Republic of Korea,* 65 FR 6585 (February 10, 2000).

[9] *Notice of Amended Final Determinations: Certain Cut-to-Length Carbon-Quality Steel Plate From India and the Republic of Korea; and Notice of Countervailing Duty Orders: Certain Cut-To-Length Carbon-Quality Steel Plate From France, India, Indonesia, Italy, and the Republic of Korea,* 65 FR 6587 (February 10, 2000).

[10] For purposes of this scope exclusion, rolling operations such as a skin pass, levelling, temper rolling or other minor rolling operations after the hot-rolling process for purposes of surface finish, flatness, shape control, or gauge control do not constitute cold-rolling sufficient to meet this exclusion.

[11] Ball bearing steels are defined as steels which contain, in addition to iron, each of the following elements by weight in the amount specified: (i) Not less than 0.95 nor more than 1.13 percent of carbon; (ii) not less than 0.22 nor more than 0.48 percent of manganese; (iii) none, or not more than 0.03 percent of sulfur; (iv) none, or not more than 0.03 percent of phosphorus; (v) not less than 0.18 nor more than 0.37 percent of silicon; (vi) not less than 1.25 nor more than 1.65 percent of chromium; (vii) none, or not more than 0.28 percent of nickel; (viii) none, or not more than 0.38 percent of copper; and (ix) none, or not more than 0.09 percent of molybdenum.

[12] Tool steels are defined as steels which contain the following combinations of elements in the quantity by weight respectively indicated: (i) More than 1.2 percent carbon and more than 10.5 percent chromium; or (ii) not less than 0.3 percent carbon and 1.25 percent or more but less than 10.5 percent chromium; or (iii) not less than 0.85 percent carbon and 1 percent to 1.8 percent, inclusive, manganese; or (iv) 0.9 percent to 1.2 percent, inclusive, chromium and 0.9 percent to 1.4 percent, inclusive, molybdenum; or (v) not less than 0.5 percent carbon and not less than 3.5 percent molybdenum; or (vi) not less than 0.5 percent carbon and not less than 5.5 percent tungsten.

[13] Silico-manganese steel is defined as steels containing by weight: (i) Not more than 0.7 percent of carbon; (ii) 0.5 percent or more but not more than 1.9 percent of manganese, and (iii) 0.6 percent or more but not more than 2.3 percent of silicon.

SUMMARY: The Department of Commerce (the Department) determines that imports of certain hot-rolled steel flat products (hot-rolled steel) from the Netherlands are being, or are likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is July 1, 2014, through June 30, 2015. The final dumping margins of sales at LTFV are listed in the "Final Determination" section of this notice.

DATES: Effective August 12, 2016.

FOR FURTHER INFORMATION CONTACT: Dmitry Vladimirov, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–0665.

SUPPLEMENTARY INFORMATION:

Background

On March 22, 2016, the Department published the *Preliminary Determination* of this antidumping duty (AD) investigation.[1] The following events occurred since the *Preliminary Determination* was issued. In June 2016, AK Steel Corporation (one of the petitioners)[2] and Tata Steel IJmuiden B.V. (TSIJ) submitted case briefs[3] and rebuttal briefs.[4] A hearing was held on June 24, 2016.

Scope of the Investigation

The products covered by this investigation are certain hot-rolled steel flat products from the Netherlands. For a complete description of the scope of this investigation, *see* the "Scope of the Investigation," in Appendix I of this notice.

Scope Comments

In the Preliminary Scope Decision Memorandum,[5] the Department set aside a period of time for parties to address scope issues in case briefs or other written comments on scope issues. In the *Preliminary Determination,* we did not modify the scope language as it appeared in the *Initiation Notice.*[6] No interested parties submitted scope comments in case or rebuttal briefs; therefore, the scope of this investigation remains unchanged for this final determination.

Analysis of the Comments Received

All issues raised in the case and rebuttal briefs by parties in this investigation are addressed in the Issues and Decision Memorandum, which is hereby adopted by this notice.[7] A list of the issues raised is attached to this notice as Appendix II. The Issues and Decision Memorandum is a public document and is on file electronically *via* Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov* and it is available to all parties in the Central Records Unit, room B–8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the Internet at *http://enforcement.trade.gov/frn/index.html.* The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

Verification

As provided in section 782(i) of the Tariff Act of 1930, as amended (the Act), in March and April 2016, the Department verified the sales and cost data reported by the mandatory respondent. We used standard verification procedures, including an examination of relevant accounting and production records, and original source documents provided by TSIJ.[8]

Changes Since the Preliminary Determination

Based on our analysis of the comments received, pre-verification corrections, and our findings at verification, we made certain changes to the margin calculations for TSIJ. For a discussion of these changes, *see* the "Margin Calculations" and "Comparisons to Fair Value" sections of the Issues and Decision Memorandum. We have also revised the all-others rate

All-Others Rate

Section 735(c)(5)(A) of the Act provides that the estimated all-others rate shall be an amount equal to the weighted-average of the estimated weighted-average dumping margins established for exporters and producers individually investigated excluding any zero or *de minimis* margins, and margins determined entirely under section 776 of the Act. The Department calculated a company-specific rate for TSIJ that is not zero, *de minimis* or determined entirely under section 776 of the Act. Therefore, for purposes of determining the "all-others" rate and pursuant to section 735(c)(5)(A) of the Act, we are using the weighted-average dumping margin calculated for TSIJ as the estimated weighted-average dumping margin assigned to all other producers and exporters of the merchandise under consideration.

Final Determination

The Department determines that the final weighted-average dumping margins are as follows:

Exporter/Producer	Weighted-average margin (percent)
Tata Steel IJmuiden B.V.	3.73
All-Others	3.73

Final Negative Determination of Critical Circumstances

On December 9, 2015, the Department preliminarily found that critical circumstances do not exist for imports of hot-rolled steel from the Netherlands.[9] Based on the final dumping margin we established for TSIJ and "all others," we are not modifying our preliminary finding for the final determination. For a complete discussion of this issue, *see* the "Critical Circumstances" section of the Issues and Decision Memorandum.

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[1] *See Certain Hot-Rolled Steel Flat Products from the Netherlands: Affirmative Preliminary Determination of Sales at Less Than Fair Value, Postponement of Final Determination and Extension of Provisional Measures,* 81 FR 15225 (March 22, 2016) (*Preliminary Determination*).

[2] AK Steel Corporation (AK Steel), ArcelorMittal USA LLC, Nucor Corporation, SSAB Enterprises, LLC, Steel Dynamics, Inc., and United States Steel Corporation (collectively, the petitioners).

[3] *See* Letter from AK Steel Corporation, "Certain Hot-Rolled Steel Flat Products From The Netherlands: Petitioner's Case Brief" (June 9, 2016); and Letter from TSIJ, "Certain Hot-Rolled Steel Flat Products From The Netherlands: Case Brief of Tata Steel IJmuiden BV" (June 9, 2016).

[4] *See* Letter from AK Steel Corporation "Certain Hot-Rolled Steel Flat Products From The Netherlands: Petitioner's Rebuttal Brief" (June 20, 2016).

[5] *See* Memorandum to Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, "Certain Hot-Rolled Steel Products From Australia, Brazil, Japan, the Netherlands, the Republic of Korea, Turkey, and the United Kingdom: Scope Comments Decision Memorandum for the Preliminary Determinations" dated March 14, 2016 (Preliminary Scope Decision Memorandum).

[6] *See Preliminary Determination* and accompanying Memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Enforcement and Compliance, entitled "Decision Memorandum for the Preliminary Determination in the Less-Than-Fair-Value Investigation of Certain Hot-Rolled Steel Flat Products from the Netherlands" at page 4. *See also Certain Hot-Rolled Steel Flat Products From Australia, Brazil, Japan, the Republic of Korea, the Netherlands, The Republic of Turkey, and the United Kingdom: Initiation of Less-Than-Fair-Value Investigations,* 80 FR 54261, 54262 (September 9, 2015) (*Initiation Notice*).

[7] *See* Memorandum from Deputy Assistant Secretary Christian Marsh to Acting Assistant Secretary Ronald K. Lorentzen entitled, "Issues and Decision Memorandum for the Final Affirmative Determination in the Less than Fair Value Investigation of Certain Hot-Rolled Steel Flat Products from the Netherlands," dated concurrently with this notice (Issues and Decision Memorandum).

[8] *See* Memorandum to the File entitled "Verification of the Sales Response of Tata Steel IJmuiden B.V. in the Less-Than-Fair-Value Investigation of Certain Hot-Rolled Steel Flat Products from the Netherlands," dated April 13, 2016, and Memorandum to the File entitled "Verification of the Cost Response of Tata Steel IJmuiden BV in the Investigation of Certain Hot-Rolled Steel Flat Products from the Netherlands," dated June 1, 2016.

Disclosure

We intend to disclose the calculations performed to interested parties within five days after the public announcement of this final determination in accordance with 19 CFR 351.224(b).

Continuation of Suspension of Liquidation

In accordance with section 735(c)(1)(B) of the Act, the Department will instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of all entries of hot-rolled steel from the Netherlands, as described in Appendix I of this notice, which were entered, or withdrawn from warehouse, for consumption on or after March 22, 2016, the date of publication of the *Preliminary Determination* of this investigation in the **Federal Register**.

Further, pursuant to section 735(c)(1)(B)(ii) of the Act, CBP shall require a cash deposit equal to the estimated amount by which normal value exceeds U.S. price, as follows: (1) For the exporter/producer listed in the table above, the cash deposit rate will be equal to the weighted-average dumping margin which the Department determined in this final determination; the cash deposit rate for the mandatory respondent listed above will be equal to the estimated weighted-average dumping margin determined in this final determination; (2) if the exporter is not a firm identified in this investigation but the producer is, then the cash deposit rate will be equal to the estimated weighted-average dumping margin established for the producer of the subject merchandise; (3) the cash deposit rate for all other producers or exporters will be 3.73 percent, as discussed in the "All Others Rate" section, above. These instructions suspending liquidation will remain in effect until further notice.

U.S. International Trade Commission Notification

In accordance with section 735(d) of the Act, we will notify the U.S. International Trade Commission (ITC) of the final affirmative determination of sales at LTFV. Because the final determination in this proceeding is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports of hot-rolled steel from the Netherlands no later than 45 days after our final determination. If the ITC determines that material injury or threat of material injury does exist, the Department will issue an antidumping duty order directing CBP to assess, upon further instruction by the Department, antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation, as discussed above in the "Continuation of Suspension of Liquidation" section. If the ITC determines that material injury or threat of material injury does not exist, the proceeding will be terminated and all cash deposits will be refunded.

Notification Regarding Administrative Protective Orders

This notice serves as a reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is subject to sanction.

This determination is issued and published pursuant to sections 735(d) and 777(i)(l) of the Act.

Dated: August 4, 2016.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The products covered by this investigation are certain hot-rolled, flat-rolled steel products, with or without patterns in relief, and whether or not annealed, painted, varnished, or coated with plastics or other non-metallic substances. The products covered do not include those that are clad, plated, or coated with metal. The products covered include coils that have a width or other lateral measurement ("width") of 12.7 mm or greater, regardless of thickness, and regardless of form of coil (*e.g.*, in successively superimposed layers, spirally oscillating, *etc.*). The products covered also include products not in coils (*e.g.*, in straight lengths) of a thickness of less than 4.75 mm and a width that is 12.7 mm or greater and that measures at least 10 times the thickness. The products described above may be rectangular, square, circular, or other shape and include products of either rectangular or non-rectangular cross-section where such cross-section is achieve subsequent to the rolling process, *i.e.*, products which have been "worked after rolling" (*e.g.*, products which have been beveled or rounded at the edges). For purposes of the width and thickness requirements referenced above:

(1) Where the nominal and actual measurements vary, a product is within the scope if application of either the nominal or actual measurement would place it within the scope based on the definitions set forth above unless the resulting measurement makes the product covered by the existing antidumping[10] or countervailing duty[11] orders on Certain Cut-To-Length Carbon-Quality Steel Plate Products From the Republic of Korea (A–580–836; C–580–837), and

(2) where the width and thickness vary for a specific product (*e.g.*, the thickness of certain products with non-rectangular cross-section, the width of certain products with non-rectangular shape, etc.), the measurement at its greatest width or thickness applies.

Steel products included in the scope of this investigation are products in which: (1) Iron predominates, by weight, over each of the other contained elements; (2) the carbon content is 2 percent or less, by weight; and (3) none of the elements listed below exceeds the quantity, by weight, respectively indicated:

- 2.50 percent of manganese, or
- 3.30 percent of silicon, or
- 1.50 percent of copper, or
- 1.50 percent of aluminum, or
- 1.25 percent of chromium, or
- 0.30 percent of cobalt, or
- 0.40 percent of lead, or
- 2.00 percent of nickel, or
- 0.30 percent of tungsten, or
- 0.80 percent of molybdenum, or
- 0.10 percent of niobium, or
- 0.30 percent of vanadium, or
- 0.30 percent of zirconium.

Unless specifically excluded, products are included in this scope regardless of levels of boron and titanium.

For example, specifically included in this scope are vacuum degassed, fully stabilized

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[9] *See Antidumping Duty Investigations of Certain Hot-Rolled Steel Flat Products From Australia, Brazil, Japan, and the Netherlands and Countervailing Duty Investigation of Certain Hot-Rolled Steel Flat Products From Brazil: Preliminary Determinations of Critical Circumstances,* 80 FR 76444, 76446–47 (December 9, 2015).

[10] *Notice of Amendment of Final Determinations of Sales at Less Than Fair Value and Antidumping Duty Orders: Certain Cut-To-Length Carbon-Quality Steel Plate Products From France, India, Indonesia, Italy, Japan and the Republic of Korea,* 65 FR 6585 (February 10, 2000).

[11] *Notice of Amended Final Determinations: Certain Cut-to-Length Carbon-Quality Steel Plate From India and the Republic of Korea; and Notice of Countervailing Duty Orders: Certain Cut-To-Length Carbon-Quality Steel Plate From France, India, Indonesia, Italy, and the Republic of Korea,* 65 FR 6587 (February 10, 2000).

(commonly referred to as interstitial-free (IF)) steels, high strength low alloy (HSLA) steels, the substrate for motor lamination steels, Advanced High Strength Steels (AHSS), and Ultra High Strength Steels (UHSS). IF steels are recognized as low carbon steels with micro-alloying levels of elements such as titanium and/or niobium added to stabilize carbon and nitrogen elements. HSLA steels are recognized as steels with micro-alloying levels of elements such as chromium, copper, niobium, titanium, vanadium, and molybdenum. The substrate for motor lamination steels contains micro-alloying levels of elements such as silicon and aluminum. AHSS and UHSS are considered high tensile strength and high elongation steels, although AHSS and UHSS are covered whether or not they are high tensile strength or high elongation steels.

Subject merchandise includes hot-rolled steel that has been further processed in a third country, including but not limited to pickling, oiling, levelling, annealing, tempering, temper rolling, skin passing, painting, varnishing, trimming, cutting, punching, and/or slitting, or any other processing that would not otherwise remove the merchandise from the scope of the investigation if performed in the country of manufacture of the hot-rolled steel.

All products that meet the written physical description, and in which the chemistry quantities do not exceed any one of the noted element levels listed above, are within the scope of this investigation unless specifically excluded. The following products are outside of and/or specifically excluded from the scope of this investigation:

- Universal mill plates (*i.e.*, hot-rolled, flat-rolled products not in coils that have been rolled on four faces or in a closed box pass, of a width exceeding 150 mm but not exceeding 1250 mm, of a thickness not less than 4.0 mm, and without patterns in relief);
- Products that have been cold-rolled (cold-reduced) after hot-rolling; [12]
- Ball bearing steels; [13]
- Tool steels; [14] and
- Silico-manganese steels; [15]

The products subject to this investigation are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers: 7208.10.1500, 7208.10.3000, 7208.10.6000, 7208.25.3000, 7208.25.6000, 7208.26.0030, 7208.26.0060, 7208.27.0030, 7208.27.0060, 7208.36.0030, 7208.36.0060, 7208.37.0030, 7208.37.0060, 7208.38.0015, 7208.38.0030, 7208.38.0090, 7208.39.0015, 7208.39.0030, 7208.39.0090, 7208.40.6030, 7208.40.6060, 7208.53.0000, 7208.54.0000, 7208.90.0000, 7210.70.3000, 7211.14.0030, 7211.14.0090, 7211.19.1500, 7211.19.2000, 7211.19.3000, 7211.19.4500, 7211.19.6000, 7211.19.7530, 7211.19.7560, 7211.19.7590, 7225.11.0000, 7225.19.0000, 7225.30.3050, 7225.30.7000, 7225.40.7000, 7225.99.0090, 7226.11.1000, 7226.11.9030, 7226.11.9060, 7226.19.1000, 7226.19.9000, 7226.91.5000, 7226.91.7000, and 7226.91.8000. The products subject to the investigation may also enter under the following HTSUS numbers: 7210.90.9000, 7211.90.0000, 7212.40.1000, 7212.40.5000, 7212.50.0000, 7214.91.0015, 7214.91.0060, 7214.91.0090, 7214.99.0060, 7214.99.0075, 7214.99.0090, 7215.90.5000, 7226.99.0180, and 7228.60.6000.

The HTSUS subheadings above are provided for convenience and U.S. Customs purposes only. The written description of the scope of the investigation is dispositive.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Critical Circumstances
IV. Scope of the Investigation
V. Margin Calculations
VI. Comparisons to Fair Value
VII. Discussion of the Issues
  Comment 1: Purchases of Raw Material Inputs
  Comment 2: G&A Expenses Ratio
  Comment 3: TSIJ's B-Slab Adjustment to Cost of Manufacturing
VIII. Recommendation

[FR Doc. 2016–19371 Filed 8–11–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–351–845]

Certain Hot-Rolled Steel Flat Products From Brazil: Final Determination of Sales at Less Than Fair Value and Final Affirmative Determination of Critical Circumstances, in Part

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) determines that certain hot-rolled steel flat products (hot-rolled steel) from Brazil are being, or are likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is July 1, 2014, through June 30, 2015. The final dumping margins of sales at LTFV are listed below in the "Final Determination" section of this notice.

DATES: Effective August 12, 2016.

FOR FURTHER INFORMATION CONTACT: Peter Zukowski, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–0189.

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[12] For purposes of this scope exclusion, rolling operations such as a skin pass, levelling, temper rolling or other minor rolling operations after the hot-rolling process for purposes of surface finish, flatness, shape control, or gauge control do not constitute cold-rolling sufficient to meet this exclusion.

[13] Ball bearing steels are defined as steels which contain, in addition to iron, each of the following elements by weight in the amount specified: (i) Not less than 0.95 nor more than 1.13 percent of carbon; (ii) not less than 0.22 nor more than 0.48 percent of manganese; (iii) none, or not more than 0.03 percent of sulfur; (iv) none, or not more than 0.03 percent of phosphorus; (v) not less than 0.18 nor more than 0.37 percent of silicon; (vi) not less than 1.25 nor more than 1.65 percent of chromium; (vii) none, or not more than 0.28 percent of nickel; (viii) none, or not more than 0.38 percent of copper; and (ix) none, or not more than 0.09 percent of molybdenum.

[14] Tool steels are defined as steels which contain the following combinations of elements in the quantity by weight respectively indicated: (i) More than 1.2 percent carbon and more than 10.5 percent chromium; or (ii) not less than 0.3 percent carbon and 1.25 percent or more but less than 10.5 percent chromium; or (iii) not less than 0.85 percent carbon and 1 percent to 1.8 percent, inclusive, manganese; or (iv) 0.9 percent to 1.2 percent, inclusive, chromium and 0.9 percent to 1.4 percent, inclusive, molybdenum; or (v) not less than 0.5 percent carbon and not less than 3.5 percent molybdenum; or (vi) not less than 0.5 percent carbon and not less than 5.5 percent tungsten.

[15] Silico-manganese steel is defined as steels containing by weight: (i) Not more than 0.7 percent of carbon; (ii) 0.5 percent or more but not more than 1.9 percent of manganese, and (iii) 0.6 percent or more but not more than 2.3 percent of silicon.

SUPPLEMENTARY INFORMATION:

Background

On March 22, 2016, the Department published the *Preliminary Determination* of this antidumping duty (AD) investigation.[1] The following events occurred since the *Preliminary Determination* was issued. In March 2016, the Department received supplemental cost responses and revised sales and cost files from Companhia Siderurgica Nacional (CSN), a mandatory respondent in this investigation. In June 2016, SSAB Enterprises, LLC, and Steel Dynamics, Inc.,[2] and CSN submitted case briefs[3] and rebuttal briefs.[4]

Scope of the Investigation

The products covered by this investigation are certain hot-rolled steel flat products from Brazil. For a complete description of the scope of this investigation, *see* the "Scope of the Investigation," in Appendix I of this notice.

Scope Comments

In accordance with the Preliminary Scope Determination,[5] the Department set aside a period of time for parties to address scope issues in case briefs or other written comments on scope issues. No interested parties submitted scope comments in case or rebuttal briefs; therefore, the scope of this investigation remains unchanged for this final determination.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties in this investigation are addressed in the Issues and Decision Memorandum, which is hereby adopted by this notice.[6] A list of the issues raised is attached to this notice as Appendix II. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov* and it is available to all parties in the Central Records Unit, room B–8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/index.html.* The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

Verification

As provided in section 782(i) of the Tariff Act of 1930, as amended (the Act), in April and May 2016, the Department verified the sales and cost data reported by CSN, pursuant to section 782(i) of the Act. We used standard verification procedures, including an examination of relevant accounting and production records, and original source documents provided by the respondent.[7]

Use of Adverse Facts Available

The Department found in the *Preliminary Determination* that Usiminas Siderurgicas de Minas Gerais S.A. (Usiminas) withheld requested information, significantly impeded the proceeding, and did not cooperate to the best of its ability in responding to the Department's requests for information.[8] Therefore, in accordance with sections 776(a)(2)(A) and (C) of the Act, 776(b) of the Act, and 19 CFR 351.308(a), the Department preliminarily determined the weighted-average dumping margin for Usiminas based on facts otherwise available with an adverse inference and preliminarily selected 34.28 percent as the adverse facts-available dumping margin for Usiminas, which is the highest margin alleged in the petition.[9] This rate was assigned to Usiminas because Usiminas failed to respond to sections B, C, and D of the Department's questionnaire in this investigation.[10]

The Department received no comments regarding its preliminary application of the adverse facts-available dumping margin to Usiminas. For the final determination, the Department has not altered its analysis or its decision to apply the adverse facts-available dumping margin to Usiminas.

Changes Since the Preliminary Determination

Based on CSN's supplemental cost responses and revised sales and cost files, our findings at verification and our analysis of the comments received, we made certain changes to the margin calculations for CSN. For a discussion of these changes, *see* the "Margin Calculations" and "Comparisons to Fair Value" sections of the Issues and Decision Memorandum. We have also revised the all-others rate.

All-Others Rate

Section 735(c)(5)(A) of the Act provides that the estimated all-others rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero and *de minimis* margins, and any margins determined entirely under section 776 of the Act. For purposes of this final determination, we are assigning 33.14 percent as the "all-others" rate, which is based on the estimated dumping margin calculated for CSN, the only mandatory respondent for which we calculated a dumping margin.[11]

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[1] *See Certain Hot-Rolled Steel Flat Products From Brazil: Affirmative Preliminary Determination of Sales at Less Than Fair Value, Postponement of Final Determination and Extension of Provisional Measures,* 81 FR 15235 (March 22, 2016) (*Preliminary Determination*).

[2] The petitioners in this case are AK Steel Corporation (AK Steel), ArcelorMittal USA LLC, Nucor Corporation, SSAB Enterprises, LLC, Steel Dynamics, Inc., and United States Steel Corporation (collectively, the petitioners). SSAB Enterprises, LLC and Steel Dynamics, Inc., submitted case and rebuttal briefs on behalf of all of the petitioners.

[3] *See* Letter from SSAB Enterprises, LLC, and Steel Dynamics, Inc., "Certain Hot-Rolled Steel Flat Products From Brazil: Petitioners' Case Brief" (June 17, 2016); Letter from CSN, "Certain Cold-Rolled Steel Flat Products from Brazil and Certain Hot-Rolled Steel Flat Products from Brazil: CSN's Case Brief" (June 17, 2016).

[4] *See* Letter from SSAB Enterprises, LLC, and Steel Dynamics, Inc., "Certain Hot-Rolled Steel Flat Products From Brazil: Petitioners' Rebuttal Brief" (June 22, 2016); Letter from CSN, "Certain Hot-Rolled Steel Flat Products from Brazil: CSN's Rebuttal Brief" (June 22, 2016).

[5] *See* Memorandum to Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, "Certain Hot-Rolled Steel Products From Australia, Brazil, Japan, the Netherlands, the Republic of Korea, Turkey, and the United Kingdom: Scope Comments Decision Memorandum for the Preliminary Determinations" dated March 14, 2016 (Preliminary Scope Decision Memorandum).

[6] *See* Memorandum to Ronald K. Lorentzen, Acting Assistant Secretary for Enforcement and Compliance, from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations "Issues and Decision Memorandum for the Final Determination of the Antidumping Duty Investigation of Certain Hot-Rolled Steel Flat Products from Brazil" (August 4, 2016) (Issues and Decision Memorandum).

[7] *See* Memoranda to the File: "Certain Hot-Rolled Steel Flat Products from Brazil: Sales Verification Report for Companhia Siderugica Nacional," dated May 20, 2016; "Certain Hot-Rolled Steel Flat Products from Brazil: Sales Verification Report for Companhia Siderugica Nacional LLC USA," dated June 2, 2016; "Verification of the Further Manufacturing Response of Companhia Siderugica Nacional S.A. in the Antidumping Duty Investigation of Hot-Rolled Steel Flat Products from Brazil," dated June 3, 2016; and, "Verification of the Cost of Production Response of Companhia Siderugica Nacional S.A. in the Antidumping Duty Investigation of Certain Hot-Rolled Steel Flat Products from Brazil," dated June 8, 2016.

[8] *See Preliminary Determination.*

[9] *Id. See also* Memorandum to the File entitled, "Certain Hot-Rolled Steel Flat Products from Brazil: Corroboration of a Rate Based on Adverse Facts Available," dated March 14, 2016.

[10] *Id.*

[11] *See* Memorandum to the File, "Antidumping Duty Investigation of Certain Hot-Rolled Steel Flat Products from Brazil: Calculation of All-Others Rate" (All-Others Rate Memorandum), dated August 4, 2016.

Final Determination

The Department determines that the final weighted-average dumping margins are as follows:

Exporter/Producer	Weighted-average margin (percent)	Cash deposit rate (percent)
Companhia Siderurgica Nacional	33.14	29.07
Usiminas Siderurgicas de Minas Gerais S.A. (Usiminas)	34.28	30.51
All-Others	33.14	29.07

Disclosure

We intend to disclose the calculations performed to interested parties within five days of the public announcement of this final determination in accordance with 19 CFR 351.224(b).

Final Affirmative Determination of Critical Circumstances, in Part

On December 9, 2015, the Department found that critical circumstances existed for merchandise exported by CSN and Usiminas, but not for "all others."[12] Based on the final sales data submitted by CSN and further analysis following the *Preliminary Determination of Critical Circumstances,* we are modifying our findings for the final determination, in part. For the final determination with respect to CSN, our analysis of the reported monthly shipment data demonstrates that shipments of hot-rolled steel by CSN during the comparison period increased by less than 15 percent over shipments during the base period, and thus, we find that critical circumstances do not exist for CSN. As discussed in the "Use of Adverse Facts Available" section above, Usiminas did not cooperate with this investigation. Thus, we based our critical circumstances determination with respect to Usiminas on AFA and find that critical circumstances exist with respect to it. For all others, we determined that the imports during the comparison period increased less than 15 percent over imports during the base period and, accordingly, that critical circumstances do not exist with respect to all other producers and exporters of hot-rolled steel from Brazil. For a complete discussion of this issue, *see* the "Final Determination of Critical Circumstances" section of the Issues and Decision Memorandum.

Continuation of Suspension of Liquidation

In accordance with section 735(c)(1)(B) of the Act, the Department will instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of all appropriate entries of hot-rolled steel from Brazil, as described in Appendix I of this notice, which were entered, or withdrawn from warehouse, for consumption on or after March 22, 2016, the date of publication of the *Preliminary Determination* of this investigation in the **Federal Register**. Because of our affirmative determination of critical circumstances for Usiminas, in accordance with section 735(a)(3) and (c)(4)(C) of the Act, suspension of liquidation of hot-rolled steel from Brazil, shall continue to apply, for Usiminas, to unliquidated entries of merchandise entered, or withdrawn from warehouse, for consumption on or after the date which is 90 days before the publication of the *Preliminary Determination.* Because we find in this final determination that critical circumstances do not exist for CSN and for exporters not individually examined and subject to the all-others rate, consistent with section 735(c)(3) of the Act, we will instruct CBP to terminate the suspension of liquidation of entries, and to liquidate without regard to antidumping duties, entries of hot-rolled steel exported by CSN and all other companies, and entered, or withdrawn from warehouse for consumption on or after December 23, 2015, and before March 22, 2016.

Further, the Department will instruct CBP to require a cash deposit equal to the estimated amount by which the normal value exceeds the U.S. price as shown above, adjusted where appropriate for export subsidies found in the final determination of the companion countervailing duty investigation. Consistent with our longstanding practice, where the product under investigation is also subject to a concurrent countervailing duty investigation, we instruct CBP to require a cash deposit equal to the amount by which the NV exceeds the U.S. price, less the amount of the countervailing duty determined to constitute any export subsidies.[13] Therefore, in the event that a countervailing duty order is issued and suspension of liquidation is resumed in the companion countervailing duty investigation on hot-rolled steel flat products from Brazil the Department will instruct CBP to require cash deposits adjusted by the amount of export subsidies, as appropriate. These adjustments are reflected in the final column of the rate chart, above.[14] Until such suspension of liquidation is resumed in the companion countervailing duty investigation, and so long as suspension of liquidation continues under this antidumping duty investigation, the cash deposit rates for this antidumping duty investigation will be the rates identified in the weighted-average margin column in the rate chart, above.

International Trade Commission Notification

In accordance with section 735(d) of the Act, we will notify the International Trade Commission (ITC) of the final affirmative determination of sales at LTFV. Because the final determination in this proceeding is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports of hot-rolled steel from Brazil no later than 45 days after our final determination. If the ITC determines that material injury or threat of material injury does not exist, the proceeding will be terminated and all cash deposits will be refunded. If the ITC determines that such injury does exist, the Department will issue an antidumping duty order directing CBP to assess, upon further instruction by the Department, antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation.

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[12] *See* "Antidumping Duty Investigations of Certain Hot-Rolled Steel Flat Products From Australia, Brazil, Japan, and the Netherlands and Countervailing Duty Investigation of Certain Hot-Rolled Steel Flat Products From Brazil: Preliminary Determinations of Critical Circumstances", 80 FR 76444 (December 9, 2015) (*Preliminary Determination of Critical Circumstances*).

[13] *See, e.g., Welded Line Pipe From the Republic of Turkey: Final Determination of Sales at Less Than Fair Value,* 80 FR 61362 (October 13, 2015) and *Notice of Final Determination of Sales at Less Than Fair Value and Negative Critical Circumstances Determination: Bottom Mount Combination Refrigerator-Freezers From the Republic of Korea,* 77 FR 17413 (March 26, 2012).

[14] *See Countervailing Duty Investigation of Certain Hot-Rolled Steel Flat Products from Brazil: Final Affirmative Determination, and Final Determination of Critical Circumstances, in Part,* dated August 4, 2016; *see* also the All-Others Rate Memorandum dated concurrently with this notice.

Notification Regarding Administrative Protective Orders

This notice serves as a reminder to parties subject to an Administrative Protective Order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a violation subject to sanction.

This determination and this notice are issued and published pursuant to sections 735(d) and 777(i)(1) of the Act.

Dated: August 4, 2016.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix I—Scope of the Investigation

The products covered by this investigation are certain hot-rolled, flat-rolled steel products, with or without patterns in relief, and whether or not annealed, painted, varnished, or coated with plastics or other non-metallic substances. The products covered do not include those that are clad, plated, or coated with metal. The products covered include coils that have a width or other lateral measurement (“width”) of 12.7 mm or greater, regardless of thickness, and regardless of form of coil (*e.g.*, in successively superimposed layers, spirally oscillating, etc.). The products covered also include products not in coils (*e.g.*, in straight lengths) of a thickness of less than 4.75 mm and a width that is 12.7 mm or greater and that measures at least 10 times the thickness. The products described above may be rectangular, square, circular, or other shape and include products of either rectangular or non-rectangular cross-section where such cross-section is achieve subsequent to the rolling process, *i.e.*, products which have been “worked after rolling” (*e.g.*, products which have been beveled or rounded at the edges). For purposes of the width and thickness requirements referenced above:

(1) Where the nominal and actual measurements vary, a product is within the scope if application of either the nominal or actual measurement would place it within the scope based on the definitions set forth above unless the resulting measurement makes the product covered by the existing antidumping[15] or countervailing duty[16] orders on Certain Cut-To-Length Carbon-Quality Steel Plate Products From the Republic of Korea (A–580–836; C–580–837), and

(2) where the width and thickness vary for a specific product (*e.g.*, the thickness of certain products with non-rectangular cross-section, the width of certain products with non-rectangular shape, etc.), the measurement at its greatest width or thickness applies.

Steel products included in the scope of this investigation are products in which: (1) Iron predominates, by weight, over each of the other contained elements; (2) the carbon content is 2 percent or less, by weight; and (3) none of the elements listed below exceeds the quantity, by weight, respectively indicated:

- 2.50 percent of manganese, or
- 3.30 percent of silicon, or
- 1.50 percent of copper, or
- 1.50 percent of aluminum, or
- 1.25 percent of chromium, or
- 0.30 percent of cobalt, or
- 0.40 percent of lead, or
- 2.00 percent of nickel, or
- 0.30 percent of tungsten, or
- 0.80 percent of molybdenum, or
- 0.10 percent of niobium, or
- 0.30 percent of vanadium, or
- 0.30 percent of zirconium.

Unless specifically excluded, products are included in this scope regardless of levels of boron and titanium.

For example, specifically included in this scope are vacuum degassed, fully stabilized (commonly referred to as interstitial-free (IF)) steels, high strength low alloy (HSLA) steels, the substrate for motor lamination steels, Advanced High Strength Steels (AHSS), and Ultra High Strength Steels (UHSS). IF steels are recognized as low carbon steels with micro-alloying levels of elements such as titanium and/or niobium added to stabilize carbon and nitrogen elements. HSLA steels are recognized as steels with micro-alloying levels of elements such as chromium, copper, niobium, titanium, vanadium, and molybdenum. The substrate for motor lamination steels contains micro-alloying levels of elements such as silicon and aluminum. AHSS and UHSS are considered high tensile strength and high elongation steels, although AHSS and UHSS are covered whether or not they are high tensile strength or high elongation steels.

Subject merchandise includes hot-rolled steel that has been further processed in a third country, including but not limited to pickling, oiling, levelling, annealing, tempering, temper rolling, skin passing, painting, varnishing, trimming, cutting, punching, and/or slitting, or any other processing that would not otherwise remove the merchandise from the scope of the investigation if performed in the country of manufacture of the hot-rolled steel.

All products that meet the written physical description, and in which the chemistry quantities do not exceed any one of the noted element levels listed above, are within the scope of this investigation unless specifically excluded. The following products are outside of and/or specifically excluded from the scope of this investigation:

- Universal mill plates (*i.e.*, hot-rolled, flat-rolled products not in coils that have been rolled on four faces or in a closed box pass, of a width exceeding 150 mm but not exceeding 1250 mm, of a thickness not less than 4.0 mm, and without patterns in relief);
- Products that have been cold-rolled (cold-reduced) after hot-rolling;[17]
- Ball bearing steels;[18]
- Tool steels;[19] and
- Silico-manganese steels;[20]

The products subject to this investigation are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers: 7208.10.1500, 7208.10.3000, 7208.10.6000, 7208.25.3000, 7208.25.6000, 7208.26.0030, 7208.26.0060, 7208.27.0030, 7208.27.0060, 7208.36.0030, 7208.36.0060, 7208.37.0030, 7208.37.0060, 7208.38.0015, 7208.38.0030, 7208.38.0090,

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[15] *Notice of Amendment of Final Determinations of Sales at Less Than Fair Value and Antidumping Duty Orders: Certain Cut-To-Length Carbon-Quality Steel Plate Products From France, India, Indonesia, Italy, Japan and the Republic of Korea*, 65 FR 6585 (February 10, 2000).

[16] *Notice of Amended Final Determinations: Certain Cut-to-Length Carbon-Quality Steel Plate From India and the Republic of Korea; and Notice of Countervailing Duty Orders: Certain Cut-To-Length Carbon-Quality Steel Plate From France, India, Indonesia, Italy, and the Republic of Korea*, 65 FR 6587 (February 10, 2000).

[17] For purposes of this scope exclusion, rolling operations such as a skin pass, levelling, temper rolling or other minor rolling operations after the hot-rolling process for purposes of surface finish, flatness, shape control, or gauge control do not constitute cold-rolling sufficient to meet this exclusion.

[18] Ball bearing steels are defined as steels which contain, in addition to iron, each of the following elements by weight in the amount specified: (i) Not less than 0.95 nor more than 1.13 percent of carbon; (ii) not less than 0.22 nor more than 0.48 percent of manganese; (iii) none, or not more than 0.03 percent of sulfur; (iv) none, or not more than 0.03 percent of phosphorus; (v) not less than 0.18 nor more than 0.37 percent of silicon; (vi) not less than 1.25 nor more than 1.65 percent of chromium; (vii) none, or not more than 0.28 percent of nickel; (viii) none, or not more than 0.38 percent of copper; and (ix) none, or not more than 0.09 percent of molybdenum.

[19] Tool steels are defined as steels which contain the following combinations of elements in the quantity by weight respectively indicated: (i) More than 1.2 percent carbon and more than 10.5 percent chromium; or (ii) not less than 0.3 percent carbon and 1.25 percent or more but less than 10.5 percent chromium; or (iii) not less than 0.85 percent carbon and 1 percent to 1.8 percent, inclusive, manganese; or (iv) 0.9 percent to 1.2 percent, inclusive, chromium and 0.9 percent to 1.4 percent, inclusive, molybdenum; or (v) not less than 0.5 percent carbon and not less than 3.5 percent molybdenum; or (vi) not less than 0.5 percent carbon and not less than 5.5 percent tungsten.

[20] Silico-manganese steel is defined as steels containing by weight: (i) Not more than 0.7 percent of carbon; (ii) 0.5 percent or more but not more than 1.9 percent of manganese, and (iii) 0.6 percent or more but not more than 2.3 percent of silicon.

7208.39.0015, 7208.39.0030, 7208.39.0090, 7208.40.6030, 7208.40.6060, 7208.53.0000, 7208.54.0000, 7208.90.0000, 7210.70.3000, 7211.14.0030, 7211.14.0090, 7211.19.1500, 7211.19.2000, 7211.19.3000, 7211.19.4500, 7211.19.6000, 7211.19.7530, 7211.19.7560, 7211.19.7590, 7225.11.0000, 7225.19.0000, 7225.30.3050, 7225.30.7000, 7225.40.7000, 7225.99.0090, 7226.11.1000, 7226.11.9030, 7226.11.9060, 7226.19.1000, 7226.19.9000, 7226.91.5000, 7226.91.7000, and 7226.91.8000. The products subject to the investigation may also enter under the following HTSUS numbers: 7210.90.9000, 7211.90.0000, 7212.40.1000, 7212.40.5000, 7212.50.0000, 7214.91.0015, 7214.91.0060, 7214.91.0090, 7214.99.0060, 7214.99.0075, 7214.99.0090, 7215.90.5000, 7226.99.0180, and 7228.60.6000.

The HTSUS subheadings above are provided for convenience and U.S. Customs purposes only. The written description of the scope of the investigation is dispositive.

Appendix II—List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the Investigation
IV. Final Determination of Critical Circumstances
V. Margin Calculations
VI. Comparisons to Fair Value
VII. Discussion of Issues
  Comment 1: Duty Drawback
  Comment 2: Inventory Carrying Costs
  Comment 3: Credit Revenue
  Comment 4: Model Match
  Comment 5: Calculation of CSN LLC's G&A Expense Ratio
  Comment 6: Whether To Use a Consolidated or Non-Consolidated Financial Expense Ratio
  Comment 7: The Market Value for Affiliated Energy Inputs
  Comment 8: Whether To Include Certain Expenses Recorded Directly to Cost of Goods Sold (COGS)
VIII. Recommendation

[FR Doc. 2016–19381 Filed 8–11–16; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–489–826]

Certain Hot-Rolled Steel Flat Products From the Republic of Turkey: Final Determination of Sales at Less Than Fair Value

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) determines that imports of certain hot-rolled steel flat products (hot-rolled steel) from the Republic of Turkey (Turkey) are being, or are likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is July 1, 2014, through June 30, 2015. The final dumping margins of sales at LTFV are listed below in the "Final Determination" section of this notice.

DATES: Effective August 12, 2016.

FOR FURTHER INFORMATION CONTACT: Toni Page or Alexander Cipolla, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–1398 or (202) 482–4956, respectively.

SUPPLEMENTARY INFORMATION:

Background

On March 22, 2016, the Department published the *Preliminary Determination* of this antidumping duty (AD) investigation.[1] The following events occurred since the *Preliminary Determination* was issued.

The Department received case and rebuttal briefs from Petitioners, Erdemir, and Colakoglu between June 7 and June 20, 2016.[2] A hearing was held on June 23, 2016.[3]

Scope of the Investigation

The products covered by this investigation are hot-rolled steel flat products from Turkey. For a full description of the scope of this investigation, *see* the "Scope of the Investigation," in Appendix I of this notice.

Scope Comments

In the Preliminary Scope Decision Memorandum,[4] the Department set aside a period of time for parties to address scope issues in case briefs or other written comments on scope issues.

In the *Preliminary Determination,* we did not modify the scope language as it appeared in the *Initiation Notice.*[5] No interested parties submitted scope comments in case or rebuttal briefs; therefore, the scope of this investigation remains unchanged for this final determination.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties in this investigation are addressed in the Final Issues and Decision Memorandum, which is hereby adopted by this notice.[6] A list of the issues raised is attached to this notice as Appendix II. The Final Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov* and it is available to all parties in the Central Records Unit, Room B–8024 of the main Department of Commerce building. In addition, a complete version of the Final Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/index.html.* The signed and electronic versions of the Final Issues and Decision Memorandum are identical in content.

Verification

As provided in section 782(i) of the Tariff Act of 1930, as amended (the Act), in March, April, and May 2016, the Department verified the sales and cost data reported by the mandatory respondents Colakoglu Metalurji A.S. (Colakoglu), Colakoglu Dis Ticaret A.S. (COTAS), and Medtrade Incorporated (Medtrade) (collectively, Colakoglu) and Eregli Demir ve Celik Fabrikalari T.A.S. (Erdemir) and Iskenderun Demir Ve Celik (Iskenderun) (collectively, Erdemir). We used standard verification procedures, including an examination of relevant accounting and production records, and original source documents provided by respondents.[7]

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[1] *See Certain Hot-Rolled Steel Flat Products From the Republic of Turkey: Affirmative Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination,* 81 FR 15231 (March 22, 2016) (*Preliminary Determination*) and accompanying Preliminary Decision Memorandum.

[2] *See* the "Table of Authorities" in the Final Issues and Decision Memorandum for a complete list of case and rebuttal briefs filed.

[3] *See* "Transcript of Hearing in the Antidumping Duty Investigation of Certain Hot-Rolled Steel Flat Products from the Republic of Turkey" (June 30, 2016).

[4] *See* Memorandum to Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, "Certain Hot-Rolled Steel Products From Australia, Brazil, Japan, the Netherlands, the Republic of Korea, Turkey, and the United Kingdom: Scope Comments Decision Memorandum for the Preliminary Determinations," dated March 14, 2016 (Preliminary Scope Decision Memorandum).

[5] *See Preliminary Determination* and accompanying Memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Enforcement and Compliance, entitled "Decision Memorandum for the Preliminary Determination in the Less-Than-Fair-Value Investigation of Certain Hot-Rolled Steel Flat Products from the Republic of Turkey" at page 5. *See also Certain Hot-Rolled Steel Flat Products From Australia, Brazil, Japan, the Republic of Korea, the Netherlands, The Republic of Turkey, and the United Kingdom: Initiation of Less-Than-Fair-Value Investigations,* 80 FR 54261, 54262 (September 9, 2015) (*Initiation Notice*).

[6] *See* Memorandum to Ronald K. Lorentzen, Acting Assistant Secretary for Enforcement and Compliance, entitled "Issues and Decision Memorandum for the Final Determination in the Antidumping Duty Investigation of Certain Hot-Rolled Steel Flat Products from the Republic of Turkey," dated August 4, 2016 (Final Issues and Decision Memorandum).

Changes Since the Preliminary Determination

Based on our analysis of the comments received and our findings at verification, we made certain changes to the margin calculations for Colakoglu and Erdemir. For a discussion of these changes, *see* the Final Issues and Decision Memorandum. We have also revised the all-others rate.

All-Others Rate

Section 735(c)(5)(A) of the Act provides that the estimated all-others rate shall be an amount equal to the weighted-average of the estimated weighted-average dumping margins established for exporters and producers individually investigated excluding any zero or *de minimis* margins, and margins determined entirely under section 776 of the Act. Where the rates for investigated companies are zero or *de minimis,* or based entirely on facts otherwise available, section 735(c)(5)(B) of the Act instructs the Department to establish an "all others" rate using "any reasonable method."

In this investigation, we calculated weighted-average dumping margins for Colakoglu and Erdemir, that are above *de minimis* and which are not based entirely on facts available. We calculated the all-others rate using a weighted-average of the dumping margins calculated for the mandatory respondents using each company's publicly-ranged values for the merchandise under consideration.[8]

Final Determination

The Department determines that the final weighted-average dumping margins are as follows:

Exporter/producer	Weighted-average margin (percent)	Cash deposit rate (percent)
Colakoglu Metalurji A.S./Colakoglu Dis Ticaret A.S.[9]	7.15	7.15
Eregli Demir ve Celik Fabrikalari T.A.S./Iskenderun Demir Ve Celik[10]	3.66	3.65
All-Others	6.67	6.67

Disclosure

We intend to disclose the calculations performed to interested parties within five days of the public announcement of this final determination in accordance with 19 CFR 351.224(b).

Continuation of Suspension of Liquidation

Pursuant to section 735(c)(1)(B) of the Act, the Department will instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of all entries of hot-rolled steel from Turkey, as described in Appendix I of this notice, which were entered, or withdrawn from warehouse, for consumption on or after March 22, 2016, the date of publication of the *Preliminary Determination* of this investigation in the **Federal Register**. We also will instruct CBP to require a cash deposit equal to the weighted-average amount by which normal value exceeds U.S. price, as indicated in the table above, adjusted, where appropriate, for export subsidies.

As noted above, where the product under investigation is also subject to a concurrent countervailing duty investigation, we instruct CBP to require a cash deposit less the amount of the countervailing duty determined to constitute any export subsidies. Therefore, in the event that a countervailing duty order is issued and suspension of liquidation is resumed in the companion countervailing duty investigation on hot-rolled steel from Turkey, the Department will instruct CBP to require cash deposits adjusted by the amount of export subsidies, as appropriate.[11] These adjustments are reflected in the "Cash Deposit Rate" column of the rate chart, above. Until such suspension of liquidation is resumed in the companion countervailing duty investigation, and so long as suspension of liquidation continues under this antidumping duty investigation, the cash deposit rates for this antidumping duty investigation will be the rates identified in the weighted-average margin column in the rate chart, above.

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[7] *See* Memorandum to the File, "Verification of the Sales Response of Colakoglu Metalurji A.S. (Metalurji), Colakoglu Dis Ticaret A.S. (COTAS), and Medtrade Incorporated (Medtrade) in the Antidumping Duty Investigation of Hot-Rolled Steel Flat Products from the Republic of Turkey," (June 1, 2016) (Colakoglu Sales Verification Report); *see also* Memoradum to the File, "Verification of the U.S. Sales Responses of Colakoglu Metalurji A.S. (Metalurji), Colakoglu Dis Ticaret A.S. (COTAS),and Medtrade Incorporated (Medtrade) in the Antidumping Duty Investigation of Hot-Rolled Steel Flat Products from the Republic of Turkey," (June 1, 2016) (Colakoglu CEP Sales Verification Report); *see also* Memoradum to the File, "Verification of the Cost Response of Colakoglu Metalurji A.S. and its Affiliates in the Antidumping Duty Investigation of Hot-Rolled Steel Flat Product from Turkey," (June 1, 2016) (Colakoglu Cost Verification Report); *see also* Memorandum to the File, "Verification of the Sales Response of Ereğli Demir ve Çelik Fabrikaları T.A.Ş. in the Antidumping Investigation of Hot Rolled Steel Flat Products from Turkey," (May 31, 2016) (Erdemir Sales Verification Report); *see also* Memorandum to the File, "Verification of the Cost Response of Eregli Demir ve Celik Fabrikalari T.A.S. and its affiliates Iskenderun Demir Ve Celik," (May 30, 2016) (Erdemir Cost Verification Report).

[8] With two respondents, we normally calculate (A) a weighted-average of the dumping margins calculated for the mandatory respondents; (B) a simple average of the dumping margins calculated for the mandatory respondents; and (C) a weighted-average of the dumping margins calculated for the mandatory respondents using each company's publicly-ranged values for the merchandise under consideration. We would compare (B) and (C) to (A) and select the rate closest to (A) as the most appropriate rate for all other companies. *See Ball Bearings and Parts Thereof From France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews, Final Results of Changed-Circumstances Review, and Revocation of an Order in Part,* 75 FR 53661, 53663 (September 1, 2010). As complete publicly ranged sales data was available, we based the all-others rate on the publically ranged sales data of the mandatory respondents. For a complete BPI explanation, please *see* Memorandum to the File, entitled "Antidumping Duty Investigation of Hot-Rolled Steel Flat Products from the Republic of Turkey: Final Determination Calculation for the 'All-Others' Rate," dated August 4, 2016 (All-Others Calculation Memorandum).

[9] As in the *Preliminary Determination,* the Department continues to find that Colakoglu Metalurji A.S. and Colakoglu Dis Ticaret A.S. are a single entity. *See* "the "Affiliation and Collapsing" section of the Preliminary Decision Memorandum.

[10] As in the *Preliminary Determination,* the Department continues to find that Eregli Demir ve Celik Fabrikalari T.A.S. and Iskenderun Demir Ve Celik are a single entity. *See* the "Affiliation and Collapsing" section of the Preliminary Decision Memorandum.

[11] *See* Memorandum to Thomas Gilgunn, Program Manager for AD/CVD Operations Office VII, entitled "Investigation of Certain Hot-Rolled Steel Flat Products from the Republic of Turkey: Final Analysis Memorandum for Ereğli Demir ve Çelik Fabrikalari T.A.Ş. and its Affiliates," dated August 4, 2016. (Erdemir Final Calculation Memorandum) in the "Adjustments to the Margin Program" section.

U.S. International Trade Commission Notification

In accordance with section 735(d) of the Act, we will notify the U.S. International Trade Commission (ITC) of the final affirmative determination of sales at LTFV. Because the final determination in this proceeding is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports of hot-rolled steel from Turkey no later than 45 days after our final determination. If the ITC determines that material injury or threat of material injury does not exist, the proceeding will be terminated and all cash deposits will be refunded. If the ITC determines that such injury does exist, the Department will issue an antidumping duty order directing CBP to assess, upon further instruction by the Department, antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation as discussed in the "Continuation of Suspension of Liquidation" section.

Notification Regarding Administrative Protective Orders

This notice serves as a reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a violation subject to sanction.

This determination and this notice are issued and published pursuant to sections 735(d) and 777(i)(1) of the Act.

Dated: August 4, 2016.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The products covered by this investigation are certain hot-rolled, flat-rolled steel products, with or without patterns in relief, and whether or not annealed, painted, varnished, or coated with plastics or other non-metallic substances. The products covered do not include those that are clad, plated, or coated with metal. The products covered include coils that have a width or other lateral measurement ("width") of 12.7 mm or greater, regardless of thickness, and regardless of form of coil (*e.g.,* in successively superimposed layers, spirally oscillating, etc.). The products covered also include products not in coils (*e.g.,* in straight lengths) of a thickness of less than 4.75 mm and a width that is 12.7 mm or greater and that measures at least 10 times the thickness. The products described above may be rectangular, square, circular, or other shape and include products of either rectangular or non-rectangular cross-section where such cross-section is achieve subsequent to the rolling process, *i.e.,* products which have been "worked after rolling" (*e.g.,* products which have been beveled or rounded at the edges). For purposes of the width and thickness requirements referenced above:

(1) Where the nominal and actual measurements vary, a product is within the scope if application of either the nominal or actual measurement would place it within the scope based on the definitions set forth above unless the resulting measurement makes the product covered by the existing antidumping [12] or countervailing duty [13] orders on Certain Cut-To-Length Carbon-Quality Steel Plate Products From the Republic of Korea (A–580–836; C–580–837), and

(2) where the width and thickness vary for a specific product (*e.g.,* the thickness of certain products with non-rectangular cross-section, the width of certain products with non-rectangular shape, etc.), the measurement at its greatest width or thickness applies.

Steel products included in the scope of this investigation are products in which: (1) Iron predominates, by weight, over each of the other contained elements; (2) the carbon content is 2 percent or less, by weight; and (3) none of the elements listed below exceeds the quantity, by weight, respectively indicated:

- 2.50 percent of manganese, or
- 3.30 percent of silicon, or
- 1.50 percent of copper, or
- 1.50 percent of aluminum, or
- 1.25 percent of chromium, or
- 0.30 percent of cobalt, or
- 0.40 percent of lead, or
- 2.00 percent of nickel, or
- 0.30 percent of tungsten, or
- 0.80 percent of molybdenum, or
- 0.10 percent of niobium, or
- 0.30 percent of vanadium, or
- 0.30 percent of zirconium.

Unless specifically excluded, products are included in this scope regardless of levels of boron and titanium.

For example, specifically included in this scope are vacuum degassed, fully stabilized (commonly referred to as interstitial-free (IF)) steels, high strength low alloy (HSLA) steels, the substrate for motor lamination steels, Advanced High Strength Steels (AHSS), and Ultra High Strength Steels (UHSS). IF steels are recognized as low carbon steels with micro-alloying levels of elements such as titanium and/or niobium added to stabilize carbon and nitrogen elements. HSLA steels are recognized as steels with micro-alloying levels of elements such as chromium, copper, niobium, titanium, vanadium, and molybdenum. The substrate for motor lamination steels contains micro-alloying levels of elements such as silicon and aluminum. AHSS and UHSS are considered high tensile strength and high elongation steels, although AHSS and UHSS are covered whether or not they are high tensile strength or high elongation steels.

Subject merchandise includes hot-rolled steel that has been further processed in a third country, including but not limited to pickling, oiling, levelling, annealing, tempering, temper rolling, skin passing, painting, varnishing, trimming, cutting, punching, and/or slitting, or any other processing that would not otherwise remove the merchandise from the scope of the investigation if performed in the country of manufacture of the hot-rolled steel.

All products that meet the written physical description, and in which the chemistry quantities do not exceed any one of the noted element levels listed above, are within the scope of this investigation unless specifically excluded. The following products are outside of and/or specifically excluded from the scope of this investigation:

- Universal mill plates (*i.e.,* hot-rolled, flat-rolled products not in coils that have been rolled on four faces or in a closed box pass, of a width exceeding 150 mm but not exceeding 1250 mm, of a thickness not less than 4.0 mm, and without patterns in relief);
- Products that have been cold-rolled (cold-reduced) after hot-rolling; [14]
- Ball bearing steels; [15]
- Tool steels; [16] and

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[12] *See Notice of Amendment of Final Determinations of Sales at Less Than Fair Value and Antidumping Duty Orders: Certain Cut-To-Length Carbon-Quality Steel Plate Products From France, India, Indonesia, Italy, Japan and the Republic of Korea,* 65 FR 6585 (February 10, 2000).

[13] *See Notice of Amended Final Determinations: Certain Cut-to-Length Carbon-Quality Steel Plate From India and the Republic of Korea; and Notice of Countervailing Duty Orders: Certain Cut-To-Length Carbon-Quality Steel Plate From France, India, Indonesia, Italy, and the Republic of Korea,* 65 FR 6587 (February 10, 2000).

[14] For purposes of this scope exclusion, rolling operations such as a skin pass, levelling, temper rolling or other minor rolling operations after the hot-rolling process for purposes of surface finish, flatness, shape control, or gauge control do not constitute cold-rolling sufficient to meet this exclusion.

[15] Ball bearing steels are defined as steels which contain, in addition to iron, each of the following elements by weight in the amount specified: (i) Not less than 0.95 nor more than 1.13 percent of carbon; (ii) not less than 0.22 nor more than 0.48 percent of manganese; (iii) none, or not more than 0.03 percent of sulfur; (iv) none, or not more than 0.03 percent of phosphorus; (v) not less than 0.18 nor more than 0.37 percent of silicon; (vi) not less than 1.25 nor more than 1.65 percent of chromium; (vii) none, or not more than 0.28 percent of nickel; (viii) none, or not more than 0.38 percent of copper; and (ix) none, or not more than 0.09 percent of molybdenum.

[16] Tool steels are defined as steels which contain the following combinations of elements in the quantity by weight respectively indicated: (i) More than 1.2 percent carbon and more than 10.5 percent chromium; or (ii) not less than 0.3 percent carbon and 1.25 percent or more but less than 10.5 percent chromium; or (iii) not less than 0.85 percent carbon and 1 percent to 1.8 percent, inclusive, manganese; or (iv) 0.9 percent to 1.2 percent, inclusive,

- Silico-manganese steels;[17]

The products subject to this investigation are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers: 7208.10.1500, 7208.10.3000, 7208.10.6000, 7208.25.3000, 7208.25.6000, 7208.26.0030, 7208.26.0060, 7208.27.0030, 7208.27.0060, 7208.36.0030, 7208.36.0060, 7208.37.0030, 7208.37.0060, 7208.38.0015, 7208.38.0030, 7208.38.0090, 7208.39.0015, 7208.39.0030, 7208.39.0090, 7208.40.6030, 7208.40.6060, 7208.53.0000, 7208.54.0000, 7208.90.0000, 7210.70.3000, 7211.14.0030, 7211.14.0090, 7211.19.1500, 7211.19.2000, 7211.19.3000, 7211.19.4500, 7211.19.6000, 7211.19.7530, 7211.19.7560, 7211.19.7590, 7225.11.0000, 7225.19.0000, 7225.30.3050, 7225.30.7000, 7225.40.7000, 7225.99.0090, 7226.11.1000, 7226.11.9030, 7226.11.9060, 7226.19.1000, 7226.19.9000, 7226.91.5000, 7226.91.7000, and 7226.91.8000. The products subject to the investigation may also enter under the following HTSUS numbers: 7210.90.9000, 7211.90.0000, 7212.40.1000, 7212.40.5000, 7212.50.0000, 7214.91.0015, 7214.91.0060, 7214.91.0090, 7214.99.0060, 7214.99.0075, 7214.99.0090, 7215.90.5000, 7226.99.0180, and 7228.60.6000.

The HTSUS subheadings above are provided for convenience and U.S. Customs and Border Protection purposes only. The written description of the scope of the investigation is dispositive.

Appendix II

List of Topics Discussed in the Final Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the Investigation
IV. Scope Comments
V. Changes Since the Preliminary Determination
VI. Margin Calculations
VII. Discussion of the Issues
  Comment 1: Colakoglu's Duty Drawback Adjustment
  Comment 2: Colakoglu's U.S. Indirect Selling Expenses
  Comment 3: Colakoglu's International Ocean Freight
  Comment 4: Colakoglu's U.S. Commissions
  Comment 5: Corrections to Colakoglu's Cost Database
  Comment 6: Colakoglu's Cost-Averaging Methodology
  Comment 7: Colakoglu's Electricity Offset
  Comment 8: Colakoglu's General and Administrative Expense Ratio
  Comment 9: Using Partial Facts Available for Erdemir's Downstream Reseller Ersem
  Comment 10: Erdemir's Date of Sale
  Comment 11: Erdemir's Unreconciled Cost
  Comment 12: Erdemir's Major-Input and Transactions-Disregarded Adjustments
  Comment 13: Erdemir's Financial Expenses
  Comment 14: Erdemir's Cost of Goods Sold Denominator
  Comment 15: Erdemir's General and Administrative Expenses
VIII. Recommendation

[FR Doc. 2016–19373 Filed 8–11–16; 8:45 am]

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chromium and 0.9 percent to 1.4 percent, inclusive, molybdenum; or (v) not less than 0.5 percent carbon and not less than 3.5 percent molybdenum; or (vi) not less than 0.5 percent carbon and not less than 5.5 percent tungsten.

[17] Silico-manganese steel is defined as steels containing by weight: (i) Not more than 0.7 percent of carbon; (ii) 0.5 percent or more but not more than 1.9 percent of manganese, and (iii) 0.6 percent or more but not more than 2.3 percent of silicon.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–920]

Lightweight Thermal Paper From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review; 2014–2015

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce ("Department") is conducting an administrative review of the antidumping duty order on lightweight thermal paper ("LWTP") from the People's Republic of China ("PRC"). The period of review ("POR") is November 1, 2014, through October 31, 2015. The review covers two exporters of subject merchandise: Jaan Huey Co. Ltd. ("Jaan Huey") and Shanghai Hanhong Paper Co., Ltd. and Hanhong Paper Co. Ltd (together, "Hanhong"). Because neither respondent participated in this review, the Department preliminarily finds that Jaan Huey and Hanhong have not demonstrated eligibility for a separate rate in this segment of the proceeding, and therefore, for the preliminary results, we are treating both as part of the PRC-wide entity. Interested parties are invited to comment on these preliminary results.

DATES: Effective August 12, 2016.

FOR FURTHER INFORMATION CONTACT: Keith Haynes, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–5139.

SUPPLEMENTARY INFORMATION:

Background

On January 7, 2016, the Department initiated the seventh administrative review of the antidumping duty order on LWTP from the PRC.[1] On February 2, 2016, the Department issued antidumping questionnaires to Jaan Huey and Hanhong. On February 16, 2016, Jaan Huey notified the Department that it would not be participating in this administrative review.[2] The Hanhong companies did not respond to the Department's request for information.

Scope of the Order

The merchandise covered by this review includes certain lightweight thermal paper, which is thermal paper with a basis weight of 70 grams per square meter (g/m^2) (with a tolerance of ± 4.0 g/m^2) or less; irrespective of dimensions;[3] with or without a base coat[4] on one or both sides; with thermal active coating(s)[5] on one or both sides that is a mixture of the dye and the developer that react and form an image when heat is applied; with or without a top coat;[6] and without an adhesive backing. Certain lightweight thermal paper is typically (but not exclusively) used in point-of-sale applications such as ATM receipts, credit card receipts, gas pump receipts, and retail store receipts. The merchandise subject to this review may be classified in the Harmonized Tariff Schedule of the United States ("HTSUS") under subheadings 3703.10.60, 4811.59.20, 4811.90.8040, 4811.90.9090, 4820.10.20, 4823.40.00, 4811.90.8030, 4811.90.8050, 4811.90.9030, and 4811.90.9050.[7] [8]

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[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 81 FR 736 (January 7, 2016) ("*Initiation Notice*").

[2] *See* letter from Jaan Huey, "Notice of Non-Participation in ADD Review: Annual Antidumping Administrative Review of Lightweight Thermal Paper from the People's Republic of China," dated February 16, 2016.

[3] LWTP is typically produced in jumbo rolls that are slit to the specifications of the converting equipment and then converted into finished slit rolls. Both jumbo and converted rolls (as well as LWTP in any other form, presentation, or dimension) are covered by the scope of these orders.

[4] A base coat, when applied, is typically made of clay and/or latex and like materials and is intended to cover the rough surface of the paper substrate and to provide insulating value.

[5] A thermal active coating is typically made of sensitizer, dye, and co-reactant.

[6] A top coat, when applied, is typically made of polyvinyl acetone, polyvinyl alcohol, and/or like materials and is intended to provide environmental protection, an improved surface for press printing, and/or wear protection for the thermal print head.

[7] HTSUS subheading 4811.90.8000 was a classification used for LWTP until January 1, 2007. Effective that date, subheading 4811.90.8000 was replaced with 4811.90.8020 (for gift wrap, a non-subject product) and 4811.90.8040 (for "other" including LWTP). HTSUS subheading 4811.90.9000 was a classification for LWTP until July 1, 2005. Effective that date, subheading 4811.90.9000 was replaced with 4811.90.9010 (for tissue paper, a non-subject product) and 4811.90.9090 (for "other," including LWTP).

[8] As of January 1, 2009, the International Trade Commission deleted HTSUS subheadings 4811.90.8040 and 4811.90.9090 and added HTSUS subheadings 4811.90.8030, 4811.90.8050,

Continued

Although HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of these orders is dispositive.

Non-Market Economy Country

The Department considers the PRC to be a nonmarket economy (''NME'') country.[9] In accordance with section 771(18)(C)(i) of the Tariff Act of 1930, as amended (''the Act''), any determination that a foreign country is an NME country shall remain in effect until revoked by the administering authority. Therefore, we continue to treat the PRC as an NME country for purposes of these preliminary results.

Application of Separate Rates in NME Proceedings

In the *Initiation Notice,* the Department notified parties of the application process by which exporters may obtain separate rate status in an NME proceeding.[10] It is the Department's policy to assign all exporters of the merchandise subject to review in NME countries a single rate unless an exporter can affirmatively demonstrate an absence of government control, both in law (*de jure*) and in fact (*de facto*), with respect to exports. To establish whether a company is sufficiently independent to be entitled to a separate, company-specific rate, the Department analyzes each exporting entity in an NME country under the test established in *Sparklers,*[11] as further developed by *Silicon Carbide.*[12] However, if the Department determines that a company is wholly foreign-owned, then an analysis of the *de jure* and *de facto* criteria is not necessary to determine whether it is independent from government control.[13]

Methodology

The Department is conducting this review in accordance with section 751 of the Act. Neither mandatory respondent cooperated to the best of its ability because neither provided a response to the Department's questionnaire. Further, neither respondent submitted a separate rate application or certification to demonstrate eligibility to receive a separate rate. Thus, the Department preliminarily determines that the application of adverse facts available (''AFA'') is warranted for these preliminary results, in accordance with section 776 of the Act and 19 CFR 351.308 and, because neither demonstrated eligibility for a separate rate, we are treating the mandatory respondents as part of the PRC-wide entity.

PRC-Wide Entity

The Department's change in policy regarding conditional review of the PRC-wide entity applies to this administrative review.[14] Under this policy, the PRC-wide entity will not be under review unless a party specifically requests, or the Department self-initiates, a review of the entity. Because no party requested a review of the PRC-wide entity in this review, the entity is not under review, and the entity's rate is not subject to change (*i.e.,* 115.29 percent).[15]

Preliminary Results of Review

The preliminary weighted-average antidumping duty margin percentage is as follows:

Producer and/or exporter	Weighted-average dumping margin (percent)
PRC-Wide Entity	115.29

Public Comment and Opportunity To Request a Hearing

Interested parties may submit case briefs within 30 days after the date of publication of these preliminary results of review in the **Federal Register**.[16] Rebuttals to case briefs must be limited to issues raised in the case briefs and must be filed within five days following the time limit for filing case briefs.[17] Parties who submit arguments are requested to submit with the argument (a) a statement of the issue, (b) a brief summary of the argument, and (c) a table of authorities.[18] Parties submitting briefs should do so pursuant to the Department's electronic filing system, ACCESS.[19]

Any interested party may request a hearing within 30 days of publication of this notice.[20] Hearing requests should contain the following information: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. Oral presentations will be limited to issues raised in the briefs. If a request for a hearing is made, parties will be notified of the time and date for the hearing to be held at the U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230.[21]

The Department intends to issue the final results of this administrative review, which will include the results of our analysis of all issues raised in the case briefs, within 120 days of publication of these preliminary results in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act.

Assessment Rates

Upon issuance of the final results, the Department will determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review. The Department intends to issue assessment instructions to CBP 15 days after the publication date of the final results of this review.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) For previously investigated or reviewed PRC and non-PRC exporters who are not under review in this segment of the proceeding but who have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recent period; (2) for all PRC

4811.90.9030, and 4811.90.9050 to the *Harmonized Tariff Schedule of the United States (2009). See Harmonized Tariff Schedule of the United States (2009),* available at <ww.usitc.gov>. These HTSUS subheadings were added to the scope of the order in LWTP's LTFV investigation.

[9] *See, e.g., Certain Kitchen Appliance Shelving and Racks from the People's Republic of China: Preliminary Results of the First Administrative Review, Preliminary Rescission, in Part, and Extension of Time Limits for the Final Results,* 76 FR 62765, 62767–68 (October 11, 2011), unchanged in *Certain Kitchen Appliance Shelving and Racks from the People's Republic of China: Final Results and Partial Rescission of First Antidumping Duty Administrative Review,* 77 FR 21734 (April 11, 2012).

[10] *See Initiation Notice.*

[11] *See Final Determination of Sales at Less Than Fair Value: Sparklers from the People's Republic of China,* 56 FR 20588 (May 6, 1991) (''*Sparklers*'').

[12] *See Notice of Final Determination of Sales at Less Than Fair Value: Silicon Carbide from the People's Republic of China,* 59 FR 22585 (May 2, 1994) (''*Silicon Carbide*'').

[13] *See, e.g., Final Results of Antidumping Duty Administrative Review: Petroleum Wax Candles from the People's Republic of China,* 72 FR 52355, 52356 (September 13, 2007).

[14] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013).

[15] *See ''Lightweight Thermal Paper from the People's Republic of China: Final Determination of Sales at Less Than Fair Value,''* 73 FR 57329 (Oct 2, 2008).

[16] *See* 19 CFR 351.309(c)(1)(ii).

[17] *See* 19 CFR 351.309(d)(1)–(2).

[18] *See* 19 CFR 351.309(c)(2), (d)(2).

[19] *See* 19 CFR 351.303 (for general filing requirements).

[20] *See* 19 CFR 351.310(c).

[21] *See* 19 CFR 351.310(d).

exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be the PRC-wide rate of 115.29 percent; and (3) for all non-PRC exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporter(s) that supplied that non-PRC exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement off antidumping duties prior to liquidation of the relevant entries during this period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This administrative review and notice are in accordance with sections 751(a)(1) and 777(i) of the Act and 19 CFR 351.213.

Dated: August 5, 2016.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2016–19258 Filed 8–11–16; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–821–811]

Ammonium Nitrate From the Russian Federation: Final Results of Sunset Review and Revocation of Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On July 1, 2016, the Department of Commerce (the Department) initiated the second sunset review of the antidumping duty order on ammonium nitrate from the Russian Federation (Russia). Because no domestic interested party filed a notice of intent to participate in response to the notice of initiation, the Department is revoking the antidumping duty order on ammonium nitrate from Russia.

DATES: Effective August 20, 2016.

FOR FURTHER INFORMATION CONTACT: David Crespo at (202) 482–3693, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On April 27, 2011, the Department terminated the agreement suspending the antidumping duty investigation and issued an antidumping duty order on ammonium nitrate from Russia.[1] On July 1, 2016, the Department initiated a sunset review of the antidumping duty *Order* pursuant to section 751(c) of the Tariff Act of 1930, as amended ("the Act").[2] We received no notice of intent to participate in response to the *Initiation Notice* from domestic interested parties by the applicable deadline.[3] As a result, the Department concludes that no domestic party intends to participate in this sunset review.[4] On July 21, 2016, we notified the International Trade Commission, in writing, that we intend to revoke the *Order*.[5]

Scope of the Order

The scope of this order includes solid, fertilizer grade ammonium nitrate products, whether prilled, granular, or in other solid form, with or without additives or coating, and with a bulk density equal to or greater than 53 pounds per cubic foot. Specifically excluded from this scope is solid ammonium nitrate with a bulk density less than 53 pounds per cubic foot (commonly referred to as industrial or explosive grade ammonium nitrate). The merchandise subject to this order is classified in the Harmonized Tariff Schedule of the United States (HTSUS) at subheadings 3102.30.00.00 and 3102.290000. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise within the scope is dispositive.

Revocation

Pursuant to section 751(c)(3)(A) of the Act and 19 CFR 351.218(d)(1)(iii)(B)(3), if no domestic interested party files a notice of intent to participate, the Department shall issue a final determination revoking the order within 90 days of the initiation of the review. Because no domestic interested party filed a notice of intent to participate in this sunset review, the Department finds that no domestic interested party is participating in this sunset review. Therefore, we are revoking the *Order*. The effective date of revocation is August 20, 2016, the fifth anniversary of the date of publication in the **Federal Register** of the *Continuation of the Order*.[6]

Pursuant to section 751(c)(3)(A) of the Act and 19 CFR 351.222(i)(2)(i), the Department intends to issue instructions to U.S. Customs and Border Protection to terminate the suspension of liquidation of entries of the merchandise subject to the order which were entered, or withdrawn from warehouse, for consumption on or after August 20, 2016. Entries of subject merchandise prior to August 20, 2016, will continue to be subject to the suspension of liquidation and requirements for deposits of estimated antidumping duties. The Department will conduct administrative reviews of the order with respect to subject merchandise entered prior to the effective date of revocation in response to appropriately filed requests for review.

These final results of the five-year (sunset) review and notice of revocation of the antidumping duty order are published in accordance with sections 751(c) and 777(i)(1) of the Act.

Dated: August 5, 2016.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2016–19248 Filed 8–11–16; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–489–827]

Countervailing Duty Investigation of Certain Hot-Rolled Steel Flat Products From the Republic of Turkey: Final Affirmative Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) determines that countervailable subsidies are being provided to producers and exporters of certain hot-rolled steel flat products (hot-rolled steel) from the Republic of Turkey (Turkey). For information on the estimated subsidy rates, *see* the "Final

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[1] *See Termination of the Suspension Agreement on Solid Fertilizer Grade Ammonium Nitrate From the Russian Federation and Notice of Antidumping Duty Order;* 76 FR 23569 (April 27, 2011) (*Order*).

[2] *See Initiation of Five-Year ("Sunset") Review;* 81 FR 43185 (July 1, 2016) (*Initiation Notice*).

[3] *See* 19 CFR 351.218(d)(1)(i).

[4] *See* 19 CFR 351.218(d)(1)(iii)(A).

[5] *See* 19 CFR 351.218(d)(1)(iii)(B)(2).

[6] *See* 19 CFR 351.222(i)(2); *see also Continuation of Antidumping Duty Order on Solid Fertilizer Grade Ammonium Nitrate From the Russian Federation,* 76 FR 49449 (August 20, 2011).

Determination'' section of this notice. The period of investigation is January 1, 2014, through December 31, 2014.

DATES: Effective August 12, 2016.

FOR FURTHER INFORMATION CONTACT: Emily Halle or Gene Calvert, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone (202) 482–0176 or (202) 482–3586, respectively.

SUPPLEMENTARY INFORMATION:

Background

The Department published the *Preliminary Determination* on January 15, 2016.[1] A summary of the events that occurred since the Department published the *Preliminary Determination,* as well as a full discussion of the issues raised by parties for this final determination, may be found in the Issues and Decision Memorandum.[2] The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov,* and is available to all parties in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed Issues and Decision Memorandum and the electronic version are identical in content.

Scope Comments

In accordance with the Preliminary Scope Determination,[3] the Department set aside a period of time for parties to address scope issues in case briefs or other written comments on scope issues.

In the *Preliminary Determination,* we did not modify the scope language as it appeared in the *Initiation Notice.*[4] No interested party submitted scope comments in case or rebuttal briefs; therefore, the scope of this investigation remains unchanged for this final determination.

Scope of the Investigation

The products covered by this investigation are hot-rolled steel from Turkey. For a complete description of the scope of this investigation, *see* the "Scope of the Investigation," in Appendix I of this notice.

Analysis of Subsidy Programs and Comments Received

The subsidy programs under investigation and the issues raised in the case and rebuttal briefs by parties in this investigation are discussed in the Issues and Decision Memorandum. A list of the issues that parties raised, and to which we responded in the Issues and Decision Memorandum, is attached to this notice at Appendix II.

Use of Adverse Facts Available

The Department, in making these findings, relied, in part, on facts available and, because one or more respondents failed to cooperate by not acting to the best of their ability, we made adverse inferences.[5] For the final determination, we are basing the countervailing duty (CVD) rate for Eregli Demir ve Celik Fabrikalari T.A.S. (Erdemir), in part, on facts otherwise available, pursuant to sections 776(a)(2)(A), (C) and (D) of the Tariff Act of 1930, as amended (the Act). Further, because the Government of Turkey did not cooperate to the best of its ability in this investigation, we also determine that an adverse inference is warranted, pursuant to section 776(b) of the Act. For further information, *see* the section "Use of Facts Otherwise Available and Adverse Inferences," in the Issues and Decision Memorandum.

Changes Since the Preliminary Determination

Based on our review and analysis of the comments received from parties, and minor corrections presented at verification, we made certain changes to the respondents' subsidy rate calculations set forth in the *Preliminary Determination.* For a discussion of these changes, *see* the Issues and Decision Memorandum and the Final Analysis Memoranda.[6]

Final Determination

In accordance with section 705(c)(1)(B)(i)(I) of the Act, we determined a countervailable subsidy rate for each individually investigated exporters/producers of the subject merchandise (*i.e.,* Erdemir and Colakoglu Dis Ticaret A.S.). Section 705(c)(5)(A)(i) of the Act states that for companies not individually investigated, we will determine an "all others" rate equal to the weighted average of the countervailable subsidy rates established for exporters and producers individually investigated, excluding any *de minimis* countervailable subsidy rates and rates determined entirely by adverse facts available. In this investigation, the only non-*de minimis* rate is the rate calculated for Erdemir. Consequently, the rate calculated for Erdemir is assigned as the "all others" rate.

We determine the estimated net countervailable subsidy rates are as follows.

Company	Subsidy rate
Colakoglu Dis Ticaret A.S.	0.34 percent (*de minimis*).
Eregli Demir ve Celik Fabrikalari T.A.S..	6.01 percent *ad valorem.*
All-Others	6.01 percent *ad valorem.*

Disclosure

We intend to disclose to parties in this proceeding the calculations performed for this final determination within five days of the date of public announcement of our final determination, in accordance with 19 CFR 351.224(b).

Suspension of Liquidation

Because the *Preliminary Determination* was negative, we did not instruct U.S. Customs and Border Protection (CBP) to suspend entries of subject merchandise. In accordance with sections 705(c)(1)(C) of the Act, we are now directing CBP to suspend liquidation of and to require the posting of a cash deposit on all imports of the subject merchandise from Turkey, other than those produced and exported by Colakoglu Dis Ticaret A.S. because its rate is *de minimis,* that are entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. The suspension of liquidation will remain in effect until further notice. In addition, pursuant to section 705(c)(1)(B)(ii) of the Act, we are directing CBP to require a cash deposit for such entries of merchandise in the amount indicated above.

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[1] *See Countervailing Duty Investigation of Certain Hot-Rolled Steel Flat Products from the Republic of Turkey: Preliminary Negative Countervailing Duty Determination and Alignment of Final Determination with Final Antidumping Duty Determination,* 81 FR 2166 (January 15, 2016) (*Preliminary Determination*).

[2] *See* Memorandum, "Issues and Decision Memorandum for the Final Determination in the Countervailing Duty Investigation of Certain Hot-Rolled Steel Flat Products from the Republic of Turkey," (Issues and Decision Memorandum), dated concurrently with this determination and hereby adopted by this notice.

[3] *See* Memorandum, "Certain Hot-Rolled Steel Products from Australia, Brazil, Japan, the Netherlands, the Republic of Korea, Turkey and the United Kingdom: Scope Comments Decision Memorandum for the Preliminary Determinations,"(March 14, 2016) (Preliminary Scope Determination).

[4] *See Preliminary Determination* and accompanying Preliminary Decision Memorandum at "Scope Comments."

[5] *See* Sections 776(a) and (b) of the Act.

[6] *See* Issues and Decision Memorandum; *see also* Memoranda, "Final Determination Analysis for Colakoglu Dis Ticaret A.S.," and "Final Determination Analysis for Eregli Demir ve Celik Fabrikalari T.A.S.," both dated concurrently with this determination and hereby adopted by this notice.

As our final determination is affirmative and our preliminary determination was negative, in accordance with section 705(b)(3) of the Act, the U.S. International Trade Commission (ITC) will determine within 75 days whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports or sales (or the likelihood of sales) for importation of the subject merchandise. We will issue a CVD order if the ITC issues a final affirmative injury determination. If the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated and all estimated duties deposited or securities posted as a result of the suspension of liquidation will be refunded or canceled.

ITC Notification

In accordance with section 705(d) of the Act, we will notify the ITC of our determination. In addition, we are making available to the ITC all non-privileged and non-proprietary information related to this investigation. We will allow the ITC access to all privileged and business proprietary information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under an administrative protective order (APO), without the written consent of the Assistant Secretary for Enforcement and Compliance.

Notification Regarding Administrative Protective Orders

In the event the ITC issues a final negative injury determination, this notice serves as the only reminder to parties subject to APO of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation that is subject to sanction.

This determination is issued and published pursuant to sections 705(d) and 777(i) of the Act and 19 CFR 351.210(c).

Dated: August 4, 2016.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The products covered by this investigation are certain hot-rolled, flat-rolled steel products, with or without patterns in relief, and whether or not annealed, painted, varnished, or coated with plastics or other non-metallic substances. The products covered do not include those that are clad, plated, or coated with metal. The products covered include coils that have a width or other lateral measurement ("width") of 12.7 mm or greater, regardless of thickness, and regardless of form of coil (*e.g.,* in successively superimposed layers, spirally oscillating, etc.). The products covered also include products not in coils (*e.g.,* in straight lengths) of a thickness of less than 4.75 mm and a width that is 12.7 mm or greater and that measures at least 10 times the thickness. The products described above may be rectangular, square, circular, or other shape and include products of either rectangular or non-rectangular cross-section where such cross-section is achieve subsequent to the rolling process, *i.e.,* products which have been "worked after rolling" (*e.g.,* products which have been beveled or rounded at the edges). For purposes of the width and thickness requirements referenced above:

(1) Where the nominal and actual measurements vary, a product is within the scope if application of either the nominal or actual measurement would place it within the scope based on the definitions set forth above unless the resulting measurement makes the product covered by the existing antidumping[7] or countervailing duty[8] orders on Certain Cut-To-Length Carbon-Quality Steel Plate Products From the Republic of Korea (A–580–836; C–580–837), and

(2) where the width and thickness vary for a specific product (*e.g.,* the thickness of certain products with non-rectangular cross-section, the width of certain products with non-rectangular shape, etc.), the measurement at its greatest width or thickness applies.

Steel products included in the scope of this investigation are products in which: (1) Iron predominates, by weight, over each of the other contained elements; (2) the carbon content is 2 percent or less, by weight; and (3) none of the elements listed below exceeds the quantity, by weight, respectively indicated:

- 2.50 percent of manganese, or
- 3.30 percent of silicon, or
- 1.50 percent of copper, or
- 1.50 percent of aluminum, or
- 1.25 percent of chromium, or
- 0.30 percent of cobalt, or
- 0.40 percent of lead, or
- 2.00 percent of nickel, or
- 0.30 percent of tungsten, or
- 0.80 percent of molybdenum, or
- 0.10 percent of niobium, or
- 0.30 percent of vanadium, or
- 0.30 percent of zirconium.

Unless specifically excluded, products are included in this scope regardless of levels of boron and titanium.

For example, specifically included in this scope are vacuum degassed, fully stabilized (commonly referred to as interstitial-free (IF)) steels, high strength low alloy (HSLA) steels, the substrate for motor lamination steels, Advanced High Strength Steels (AHSS), and Ultra High Strength Steels (UHSS). IF steels are recognized as low carbon steels with micro-alloying levels of elements such as titanium and/or niobium added to stabilize carbon and nitrogen elements. HSLA steels are recognized as steels with micro-alloying levels of elements such as chromium, copper, niobium, titanium, vanadium, and molybdenum. The substrate for motor lamination steels contains micro-alloying levels of elements such as silicon and aluminum. AHSS and UHSS are considered high tensile strength and high elongation steels, although AHSS and UHSS are covered whether or not they are high tensile strength or high elongation steels.

Subject merchandise includes hot-rolled steel that has been further processed in a third country, including but not limited to pickling, oiling, levelling, annealing, tempering, temper rolling, skin passing, painting, varnishing, trimming, cutting, punching, and/or slitting, or any other processing that would not otherwise remove the merchandise from the scope of the investigation if performed in the country of manufacture of the hot-rolled steel.

All products that meet the written physical description, and in which the chemistry quantities do not exceed any one of the noted element levels listed above, are within the scope of this investigation unless specifically excluded. The following products are outside of and/or specifically excluded from the scope of this investigation:

- Universal mill plates (*i.e.,* hot-rolled, flat-rolled products not in coils that have been rolled on four faces or in a closed box pass, of a width exceeding 150 mm but not exceeding 1250 mm, of a thickness not less than 4.0 mm, and without patterns in relief);
- Products that have been cold-rolled (cold-reduced) after hot-rolling;[9]
- Ball bearing steels;[10]

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[7] *Notice of Amendment of Final Determinations of Sales at Less Than Fair Value and Antidumping Duty Orders: Certain Cut-To-Length Carbon-Quality Steel Plate Products From France, India, Indonesia, Italy, Japan and the Republic of Korea,* 65 FR 6585 (February 10, 2000).

[8] *Notice of Amended Final Determinations: Certain Cut-to-Length Carbon-Quality Steel Plate From India and the Republic of Korea; and Notice of Countervailing Duty Orders: Certain Cut-To-Length Carbon-Quality Steel Plate From France, India, Indonesia, Italy, and the Republic of Korea,* 65 FR 6587 (February 10, 2000).

[9] For purposes of this scope exclusion, rolling operations such as a skin pass, levelling, temper rolling or other minor rolling operations after the hot-rolling process for purposes of surface finish, flatness, shape control, or gauge control do not constitute cold-rolling sufficient to meet this exclusion.

[10] Ball bearing steels are defined as steels which contain, in addition to iron, each of the following elements by weight in the amount specified: (i) Not

Continued

- Tool steels;[11] and
- Silico-manganese steels;[12]

The products subject to this investigation are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers: 7208.10.1500, 7208.10.3000, 7208.10.6000, 7208.25.3000, 7208.25.6000, 7208.26.0030, 7208.26.0060, 7208.27.0030, 7208.27.0060, 7208.36.0030, 7208.36.0060, 7208.37.0030, 7208.37.0060, 7208.38.0015, 7208.38.0030, 7208.38.0090, 7208.39.0015, 7208.39.0030, 7208.39.0090, 7208.40.6030, 7208.40.6060, 7208.53.0000, 7208.54.0000, 7208.90.0000, 7210.70.3000, 7211.14.0030, 7211.14.0090, 7211.19.1500, 7211.19.2000, 7211.19.3000, 7211.19.4500, 7211.19.6000, 7211.19.7530, 7211.19.7560, 7211.19.7590, 7225.11.0000, 7225.19.0000, 7225.30.3050, 7225.30.7000, 7225.40.7000, 7225.99.0090, 7226.11.1000, 7226.11.9030, 7226.11.9060, 7226.19.1000, 7226.19.9000, 7226.91.5000, 7226.91.7000, and 7226.91.8000. The products subject to the investigation may also enter under the following HTSUS numbers: 7210.90.9000, 7211.90.0000, 7212.40.1000, 7212.40.5000, 7212.50.0000, 7214.91.0015, 7214.91.0060, 7214.91.0090, 7214.99.0060, 7214.99.0075, 7214.99.0090, 7215.90.5000, 7226.99.0180, and 7228.60.6000.

The HTSUS subheadings above are provided for convenience and U.S. Customs and Border Protection purposes only. The written description of the scope of the investigation is dispositive.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the Investigation
IV. Scope Comments
V. Subsidies Valuation Information
VI. Benchmarks and Interest Rates
VII. Use of Facts Otherwise Available and Adverse Inferences
VIII. Analysis of Programs
IX. Analysis of Comments
  Comment 1: Whether Changes in the Ownership (CIO) of Erdemir's Affiliates Resulted in Countervailable Subsidies to Erdemir
  Comment 2: Whether the Government of Turkey's (GOT's) Sale of Erdemir to OYAK Resulted in a Privatization that Extinguished the Benefits of Prior Subsidies to Erdemir
  Comment 3: Export Sales Denominator for COTAS and Colakoglu Metalurji
  Comment 4: COTAS's Rediscount Program Benchmark
  Comment 5: Whether the Department Should Correct Certain Errors in Erdemir's Preliminary Calculations
X. Recommendation

[FR Doc. 2016–19379 Filed 8–11–16; 8:45 am]

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less than 0.95 nor more than 1.13 percent of carbon; (ii) not less than 0.22 nor more than 0.48 percent of manganese; (iii) none, or not more than 0.03 percent of sulfur; (iv) none, or not more than 0.03 percent of phosphorus; (v) not less than 0.18 nor more than 0.37 percent of silicon; (vi) not less than 1.25 nor more than 1.65 percent of chromium; (vii) none, or not more than 0.28 percent of nickel; (viii) none, or not more than 0.38 percent of copper; and (ix) none, or not more than 0.09 percent of molybdenum.

[11] Tool steels are defined as steels which contain the following combinations of elements in the quantity by weight respectively indicated: (i) More than 1.2 percent carbon and more than 10.5 percent chromium; or (ii) not less than 0.3 percent carbon and 1.25 percent or more but less than 10.5 percent chromium; or (iii) not less than 0.85 percent carbon and 1 percent to 1.8 percent, inclusive, manganese; or (iv) 0.9 percent to 1.2 percent, inclusive, chromium and 0.9 percent to 1.4 percent, inclusive, molybdenum; or (v) not less than 0.5 percent carbon and not less than 3.5 percent molybdenum; or (vi) not less than 0.5 percent carbon and not less than 5.5 percent tungsten.

[12] Silico-manganese steel is defined as steels containing by weight: (i) Not more than 0.7 percent of carbon; (ii) 0.5 percent or more but not more than 1.9 percent of manganese, and (iii) 0.6 percent or more but not more than 2.3 percent of silicon.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–412–825]

Certain Hot-Rolled Steel Flat Products From the United Kingdom: Final Determination of Sales at Less Than Fair Value

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) determines that imports of certain hot-rolled steel flat products (hot-rolled steel) from the United Kingdom are being, or are likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is July 1, 2014, through June 30, 2015. The final dumping margins of sales at LTFV are listed below in the "Final Determination" section of this notice.

DATES: Effective August 12, 2016.

FOR FURTHER INFORMATION CONTACT: Catherine Cartsos, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–1757.

SUPPLEMENTARY INFORMATION:

Background

On March 22, 2016, the Department published the *Preliminary Determination* of this antidumping duty (AD) investigation.[1] The following events occurred since the *Preliminary Determination* was issued.

In March 2016, the Department received supplemental cost responses and revised sales files from Tata Steel UK Ltd. (TSUK), the sole mandatory respondent in this investigation.[2]

In June 2016, AK Steel (one of the petitioners),[3] and TSUK submitted case briefs[4] and rebuttal briefs.[5] A hearing was held on June 21, 2016.

Scope of the Investigation

The products covered by this investigation are certain hot-rolled steel flat products from the United Kingdom. For a complete description of the scope of this investigation, *see* the "Scope of the Investigation," in Appendix I of this notice.

Scope Comments

In the Preliminary Scope Decision Memorandum,[6] the Department set aside a period of time for parties to address scope issues in case briefs or other written comments on scope issues.

In the *Preliminary Determination,* we did not modify the scope language as it appeared in the *Initiation Notice.*[7] No interested parties submitted scope comments in case or rebuttal briefs; therefore, the scope of this investigation remains unchanged for this final determination.

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[1] *See Certain Hot-Rolled Steel Flat Products From the United Kingdom: Affirmative Preliminary Determination of Sales at Less Than Fair Value, Postponement of Final Determination and Extension of Provisional Measures,* 81 FR 15244 (March 22, 2016) (*Preliminary Determination*).

[2] *See* Letter from TSUK, "Antidumping Duty Investigation of Certain Hot-Rolled Steel Flat Products from the United Kingdom: TSUK's Section D Second Supplemental Questionnaire Response" (March 22, 2016). *See also* Letter from TSUK, "Antidumping Duty Investigation of Certain Hot-Rolled Steel Flat Products from the United Kingdom: TSUK's Submission of Revised Sales Files Due to Minor Corrections Presented at Sales Verification" (March 25, 2016).

[3] AK Steel Corporation (AK Steel), ArcelorMittal USA LLC, Nucor Corporation, SSAB Enterprises, LLC, Steel Dynamics, Inc., and United States Steel Corporation (collectively, the petitioners).

[4] *See* Letter from the petitioners, "Certain Hot-Rolled Steel Flat Products From The United Kingdom/Petitioner's Case Brief" (June 8, 2016); and Letter from TSUK, "Antidumping Duty Investigation of Certain Hot-Rolled Steel Flat Products from the United Kingdom: Case Brief of Tata Steel UK Ltd. and Tata Steel International (Americas) Inc." (June 8, 2016).

[5] *See* Letter from the petitioners, "Certain Hot-Rolled Steel Flat Products From The United Kingdom/Petitioner's Rebuttal Brief" (June 13, 2016); and Letter from TSUK, "Antidumping Duty Investigation of Certain Hot-Rolled Steel Flat Products from the United Kingdom: Rebuttal Brief of Tata Steel UK Ltd. and Tata Steel International (Americas) Inc." (June 13, 2016).

[6] *See* Memorandum to Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, "Certain Hot-Rolled Steel Products From Australia, Brazil, Japan, the Netherlands, the Republic of Korea, Turkey, and the United Kingdom: Scope Comments Decision Memorandum for the Preliminary Determinations," dated March 14, 2016 (Preliminary Scope Decision Memorandum).

[7] *See Preliminary Determination* and accompanying Memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Enforcement and Compliance, entitled "Decision Memorandum for the Preliminary Determination in the Less-Than-

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties in this investigation are addressed in the Issues and Decision Memorandum, which is hereby adopted by this notice.[8] A list of the issues raised is attached to this notice as Appendix II. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov* and it is available to all parties in the Central Records Unit, room B–8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/index.html.* The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

Verification

As provided in section 782(i) of the Tariff Act of 1930, as amended (the Act), in March and April 2016, the Department verified the sales and cost data reported by the mandatory respondent. We used standard verification procedures, including an examination of relevant accounting and production records, and original source documents provided by the respondent.[9]

Changes Since the Preliminary Determination

Based on our analysis of the comments received and our findings at verification, we made certain changes to the margin calculations for TSUK. For a discussion of these changes, *see* the "Margin Calculations" and "Comparisons to Fair Value" sections of the Issues and Decision Memorandum. We have also revised the all-others rate.

All-Others Rate

Section 735(c)(5)(A) of the Act provides that the estimated all-others rate shall be an amount equal to the weighted-average of the estimated weighted-average dumping margins established for exporters and producers individually investigated excluding any zero or *de minimis* margins, and margins determined entirely under section 776 of the Act. We calculated a company-specific rate for Tata Steel UK Ltd. that is not zero, *de minimis* or determined entirely under section 776 of the Act. Therefore, for purposes of determining the "all-others" rate and pursuant to section 735(c)(5)(A) of the Act, we are using the weighted-average dumping margin calculated for Tata Steel UK Ltd. as the estimated weighted-average dumping margin assigned to all other producers and exporters of the merchandise under consideration.

Final Determination

The Department determines that the final weighted-average dumping margins are as follows:

Exporter/producer	Weighted-average margin (percent)
Tata Steel UK Ltd.	33.06
All-Others	33.06

Disclosure

We intend to disclose the calculations performed to interested parties within five days of the public announcement of this final determination in accordance with 19 CFR 351.224(b).

Continuation of Suspension of Liquidation

In accordance with section 735(c)(1)(B) of the Act, the Department will instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of all appropriate entries of hot-rolled steel from the United Kingdom, as described in Appendix I of this notice, which were entered, or withdrawn from warehouse, for consumption on or after March 22, 2016, the date of publication of the *Preliminary Determination* of this investigation in the **Federal Register**.

Further, pursuant to section 735(c)(1)(B)(ii) of the Act, CBP shall require a cash deposit equal to the estimated amount by which the normal value exceeds the U.S. price, as follows: (1) For the exporter/producer listed in the table above, the cash deposit rate will be equal to the weighted average dumping margin which the Department determined in this final determination; (2) if the exporter is not a firm identified in this investigation but the producer is, the rate will be the rate established for the producer of the subject merchandise; (3) the rate for all other producers or exporters will be 33.06 percent, as discussed in the "All Others Rate" section, above. These instructions suspending liquidation will remain in effect until further notice.

U.S. International Trade Commission Notification

In accordance with section 735(d) of the Act, we will notify the U.S. International Trade Commission (ITC) of the final affirmative determination of sales at LTFV. Because the final determination in this proceeding is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports of hot-rolled steel from the United Kingdom no later than 45 days after our final determination. If the ITC determines that material injury or threat of material injury does not exist, the proceeding will be terminated and all cash deposits will be refunded. If the ITC determines that such injury does exist, the Department will issue an antidumping duty order directing CBP to assess, upon further instruction by the Department, antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation, as discussed above in the "Continuation of Suspension of Liquidation" section. If the ITC determines that material injury or threat of material injury does not exist, the proceeding will be terminated and all cash deposits will be refunded.

Notification Regarding Administrative Protective Orders

This notice serves as a reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the

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Fair-Value Investigation of Certain Hot-Rolled Steel Flat Products from the United Kingdom" at page 4. *See also Certain Hot-Rolled Steel Flat Products From Australia, Brazil, Japan, the Republic of Korea, the Netherlands, The Republic of Turkey, and the United Kingdom: Initiation of Less-Than-Fair-Value Investigations,* 80 FR 54261, 54262 (September 9, 2015) (*Initiation Notice*).

[8] *See* Memorandum to Ronald K. Lorentzen, Acting Assistant Secretary for Enforcement and Compliance, from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations "Issues and Decision Memorandum for the Final Determination of the Antidumping Duty Investigation of Certain Hot-Rolled Steel Flat Products from the United Kingdom" (August 4, 2016) (Issues and Decision Memorandum).

[9] *See* Memorandum to the File entitled "Certain Hot-Rolled Steel Flat Products from the United Kingdom: Home-Market and Export-Price Sales Verification of Tata Steel UK Ltd.," dated April 12, 2016, Memorandum to the File entitled "Certain Hot-Rolled Steel Flat Products from the United Kingdom: Constructed-Export-Price Sales Verification of Tata Steel UK Ltd.," dated May 18, 2016, and Memorandum to the File entitled "Verification of the Cost Response of Tata Steel UK Ltd. in the Antidumping Duty Investigation of Certain Hot-Rolled Steel Flat Products from the United Kingdom," dated May 31, 2016.

disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a violation subject to sanction.

This determination and this notice are issued and published pursuant to sections 735(d) and 777(i)(1) of the Act.

Dated: August 4, 2016.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The products covered by this investigation are certain hot-rolled, flat-rolled steel products, with or without patterns in relief, and whether or not annealed, painted, varnished, or coated with plastics or other non-metallic substances. The products covered do not include those that are clad, plated, or coated with metal. The products covered include coils that have a width or other lateral measurement ("width") of 12.7 mm or greater, regardless of thickness, and regardless of form of coil (*e.g.*, in successively superimposed layers, spirally oscillating, etc.). The products covered also include products not in coils (*e.g.*, in straight lengths) of a thickness of less than 4.75 mm and a width that is 12.7 mm or greater and that measures at least 10 times the thickness. The products described above may be rectangular, square, circular, or other shape and include products of either rectangular or non-rectangular cross-section where such cross-section is achieve subsequent to the rolling process, *i.e.*, products which have been "worked after rolling" (*e.g.*, products which have been beveled or rounded at the edges). For purposes of the width and thickness requirements referenced above:

(1) Where the nominal and actual measurements vary, a product is within the scope if application of either the nominal or actual measurement would place it within the scope based on the definitions set forth above unless the resulting measurement makes the product covered by the existing antidumping [10] or countervailing duty [11] orders on Certain Cut-To-Length Carbon-Quality Steel Plate Products From the Republic of Korea (A–580–836; C–580–837), and

(2) where the width and thickness vary for a specific product (*e.g.*, the thickness of certain products with non-rectangular cross-section, the width of certain products with non-rectangular shape, etc.), the measurement at its greatest width or thickness applies.

Steel products included in the scope of this investigation are products in which: (1) Iron predominates, by weight, over each of the other contained elements; (2) the carbon content is 2 percent or less, by weight; and (3) none of the elements listed below exceeds the quantity, by weight, respectively indicated:

- 2.50 percent of manganese, or
- 3.30 percent of silicon, or
- 1.50 percent of copper, or
- 1.50 percent of aluminum, or
- 1.25 percent of chromium, or
- 0.30 percent of cobalt, or
- 0.40 percent of lead, or
- 2.00 percent of nickel, or
- 0.30 percent of tungsten, or
- 0.80 percent of molybdenum, or
- 0.10 percent of niobium, or
- 0.30 percent of vanadium, or
- 0.30 percent of zirconium.

Unless specifically excluded, products are included in this scope regardless of levels of boron and titanium.

For example, specifically included in this scope are vacuum degassed, fully stabilized (commonly referred to as interstitial-free (IF)) steels, high strength low alloy (HSLA) steels, the substrate for motor lamination steels, Advanced High Strength Steels (AHSS), and Ultra High Strength Steels (UHSS). IF steels are recognized as low carbon steels with micro-alloying levels of elements such as titanium and/or niobium added to stabilize carbon and nitrogen elements. HSLA steels are recognized as steels with micro-alloying levels of elements such as chromium, copper, niobium, titanium, vanadium, and molybdenum. The substrate for motor lamination steels contains micro-alloying levels of elements such as silicon and aluminum. AHSS and UHSS are considered high tensile strength and high elongation steels, although AHSS and UHSS are covered whether or not they are high tensile strength or high elongation steels.

Subject merchandise includes hot-rolled steel that has been further processed in a third country, including but not limited to pickling, oiling, levelling, annealing, tempering, temper rolling, skin passing, painting, varnishing, trimming, cutting, punching, and/or slitting, or any other processing that would not otherwise remove the merchandise from the scope of the investigation if performed in the country of manufacture of the hot-rolled steel.

All products that meet the written physical description, and in which the chemistry quantities do not exceed any one of the noted element levels listed above, are within the scope of this investigation unless specifically excluded. The following products are outside of and/or specifically excluded from the scope of this investigation:

- Universal mill plates (*i.e.*, hot-rolled, flat-rolled products not in coils that have been rolled on four faces or in a closed box pass, of a width exceeding 150 mm but not exceeding 1250 mm, of a thickness not less than 4.0 mm, and without patterns in relief);
- Products that have been cold-rolled (cold-reduced) after hot-rolling; [12]
- Ball bearing steels; [13]
- Tool steels; [14] and
- Silico-manganese steels; [15]

The products subject to this investigation are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers: 7208.10.1500, 7208.10.3000, 7208.10.6000, 7208.25.3000, 7208.25.6000, 7208.26.0030, 7208.26.0060, 7208.27.0030, 7208.27.0060, 7208.36.0030, 7208.36.0060, 7208.37.0030, 7208.37.0060, 7208.38.0015, 7208.38.0030, 7208.38.0090, 7208.39.0015, 7208.39.0030, 7208.39.0090, 7208.40.6030, 7208.40.6060, 7208.53.0000, 7208.54.0000, 7208.90.0000, 7210.70.3000, 7211.14.0030, 7211.14.0090, 7211.19.1500, 7211.19.2000, 7211.19.3000, 7211.19.4500, 7211.19.6000, 7211.19.7530, 7211.19.7560, 7211.19.7590, 7225.11.0000, 7225.19.0000, 7225.30.3050, 7225.30.7000, 7225.40.7000, 7225.99.0090, 7226.11.1000, 7226.11.9030, 7226.11.9060, 7226.19.1000, 7226.19.9000, 7226.91.5000, 7226.91.7000, and 7226.91.8000. The products subject to the investigation may also enter under the following HTSUS numbers: 7210.90.9000, 7211.90.0000, 7212.40.1000, 7212.40.5000, 7212.50.0000, 7214.91.0015, 7214.91.0060, 7214.91.0090, 7214.99.0060, 7214.99.0075, 7214.99.0090, 7215.90.5000, 7226.99.0180, and 7228.60.6000.

The HTSUS subheadings above are provided for convenience and U.S. Customs purposes only. The written description of the scope of the investigation is dispositive.

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[10] *Notice of Amendment of Final Determinations of Sales at Less Than Fair Value and Antidumping Duty Orders: Certain Cut-To-Length Carbon-Quality Steel Plate Products From France, India, Indonesia, Italy, Japan and the Republic of Korea*, 65 FR 6585 (February 10, 2000).

[11] *Notice of Amended Final Determinations: Certain Cut-to-Length Carbon-Quality Steel Plate From India and the Republic of Korea; and Notice of Countervailing Duty Orders: Certain Cut-To-Length Carbon-Quality Steel Plate From France, India, Indonesia, Italy, and the Republic of Korea*, 65 FR 6587 (February 10, 2000).

[12] For purposes of this scope exclusion, rolling operations such as a skin pass, levelling, temper rolling or other minor rolling operations after the hot-rolling process for purposes of surface finish, flatness, shape control, or gauge control do not constitute cold-rolling sufficient to meet this exclusion.

[13] Ball bearing steels are defined as steels which contain, in addition to iron, each of the following elements by weight in the amount specified: (i) Not less than 0.95 nor more than 1.13 percent of carbon; (ii) not less than 0.22 nor more than 0.48 percent of manganese; (iii) none, or not more than 0.03 percent of sulfur; (iv) none, or not more than 0.03 percent of phosphorus; (v) not less than 0.18 nor more than 0.37 percent of silicon; (vi) not less than 1.25 nor more than 1.65 percent of chromium; (vii) none, or not more than 0.28 percent of nickel; (viii) none, or not more than 0.38 percent of copper; and (ix) none, or not more than 0.09 percent of molybdenum.

[14] Tool steels are defined as steels which contain the following combinations of elements in the quantity by weight respectively indicated: (i) More than 1.2 percent carbon and more than 10.5 percent chromium; or (ii) not less than 0.3 percent carbon and 1.25 percent or more but less than 10.5 percent chromium; or (iii) not less than 0.85 percent carbon and 1 percent to 1.8 percent, inclusive, manganese; or (iv) 0.9 percent to 1.2 percent, inclusive, chromium and 0.9 percent to 1.4 percent, inclusive, molybdenum; or (v) not less than 0.5 percent carbon and not less than 3.5 percent molybdenum; or (vi) not less than 0.5 percent carbon and not less than 5.5 percent tungsten.

[15] Silico-manganese steel is defined as steels containing by weight: (i) Not more than 0.7 percent of carbon; (ii) 0.5 percent or more but not more than 1.9 percent of manganese, and (iii) 0.6 percent or more but not more than 2.3 percent of silicon.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

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II. Background
III. Scope of the Investigation
IV. Margin Calculations
V. Comparisons to Fair Value
VI. Discussion of Issues
  Comment 1: Total Adverse Facts Available
  Comment 2: Level of Trade
  Comment 3: Home-Market Freight Revenue
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  Comment 5: Restructuring and Impairment Costs
  Comment 6: Raw Material Costs
  Comment 7: Energy Costs
  Comment 8: Partial Adverse Facts Available for Certain Sales
  Comment 9: Verification Correction
VII. Recommendation

[FR Doc. 2016–19374 Filed 8–11–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–580–884]

Countervailing Duty Investigation of Certain Hot-Rolled Steel Flat Products From the Republic of Korea: Final Affirmative Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) determines that countervailable subsidies are being provided to producers/exporters of certain hot-rolled steel flat products (hot-rolled steel) from the Republic of Korea (Korea). For information on the subsidy rates, *see* the "Final Determination" section of this notice. The period of investigation is January 1, 2014, through December 31, 2014.

DATES: Effective August 12, 2016.

FOR FURTHER INFORMATION CONTACT: Katie Marksberry, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone (202) 482–7906.

SUPPLEMENTARY INFORMATION:

Background

The Department published the *Preliminary Determination* on January 15, 2016.[1] A summary of events that occurred since the Department published the *Preliminary Determination*, as well as a full discussion of the issues raised by parties for this final determination, may be found in the Issues and Decision Memorandum.[2] The Issues and Decision Memorandum is a public document and is on file electronically *via* Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov*, and is available to all parties in the Central Records Unit, Room B8024, of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/*. The signed Issues and Decision Memorandum and the electronic version are identical in content.

Scope of the Investigation

The products covered by this investigation are hot-rolled steel flat products from Korea. For a complete description of the scope of this investigation, *see* the "Scope of the Investigation," in Appendix II of this notice.

Analysis of Subsidy Programs and Comments Received

The subsidy programs under investigation and the issues raised in the case and rebuttal briefs by parties in this investigation are discussed in the Issues and Decision Memorandum. A list of the issues that parties raised, and to which we responded in the Issues and Decision Memorandum, is attached to this notice as Appendix I.

Use of Adverse Facts Available

In making this final determination, the Department relied, in part, on facts available and, because POSCO and Hyundai Steel Co., Ltd. (Hyundai Steel) did not act to the best of their ability in responding to the Department's requests for information, we drew an adverse inference where appropriate in selecting from among the facts otherwise available.[3] Specifically, we find that the application of adverse facts available is warranted for POSCO for its failure to report certain cross-owned input suppliers, and facilities located in a foreign economic zone (FEZ). We are also applying adverse facts available to POSCO's affiliated trading company, Daewoo International Corporation (DWI)[4] for certain loans presented at verification. Further, we find that the application of adverse facts available is warranted for Hyundai Steel for its failure to report its location in an FEZ. For further information, *see* the section "Use of Facts Otherwise Available and Adverse Inferences" in the accompanying Issues and Decision Memorandum.

Changes Since the Preliminary Determination

Based on our analysis of the comments received from parties and the minor corrections presented, and additional items discovered at verification, we made certain changes to the respondents' subsidy rate calculations. For a discussion of these changes, *see* the Issues and Decision Memorandum.

Final Determination

In accordance with section 705(c)(1)(B)(i) of the Act, we calculated a rate for POSCO and Hyundai Steel, the two exporters/producers of subject merchandise selected for individual examination in this investigation.

In accordance with sections 705(c)(1)(B)(i)(I) and 705(c)(5)(A) of the Act, for companies not individually investigated, we apply an "all-others" rate, which is normally calculated by weighting the subsidy rates of the individual companies selected as respondents with those companies' export sales of the subject merchandise to the United States. Under section 705(c)(5)(A)(i) of the Act, the all-others rate should exclude zero and *de minimis* rates calculated for the exporters and producers individually investigated, and any rates determined entirely under section 776 of the Act. Therefore, we have excluded the rate calculated for POSCO because it was determined entirely under section 776 of the Act. Thus, for the "all-others" rate, we applied the rate calculated for Hyundai Steel.

Company	Subsidy rate (percent)
POSCO	57.04
Hyundai Steel Co., Ltd.	3.89
All-Others	3.89

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[1] *See Countervailing Duty Investigation of Certain Hot-Rolled Steel Flat Products From the Republic of Korea: Preliminary Negative Determination and Alignment of Final Determination With Final Antidumping Duty Determination*, 81 FR 2172 (January 15, 2016) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *See* Memorandum to Paul Piquado, "Issues and Decision Memorandum for the Final Determination in the Countervailing Duty Investigation of Certain Hot-Rolled Steel Flat Products from the Republic of Korea," dated August 4, 2016 (Issues and Decision Memorandum).

[3] *See* sections 776(a) and (b) of the Act.

[4] POSCO reported at verification that DWI changed its name to POSCO Daewoo Corporation (PDC) in March 2016. *See* IDM at 6.

Disclosure

We intend to disclose to parties in this proceeding the calculations performed for this final determination within five days of the date of public announcement of our final determination, in accordance with 19 CFR 351.224(b).

Suspension of Liquidation

In the *Preliminary Determination*, the total net countervailable subsidy rates for the individually examined respondents were *de minimis* and, therefore, we did not suspend liquidation of entries of certain hot-rolled steel flat products from the Republic of Korea. However, as the estimated subsidy rates for the examined companies are above *de minimis* in this final determination, we are directing U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of hot-rolled steel from Korea that are entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**, and to require a cash deposit for such entries of merchandise in the amounts indicated above. The suspension of liquidation will remain in effect until further notice.

If the U.S. International Trade Commission (ITC) issues a final affirmative injury determination, we will issue a CVD order and instruct CBP to require a cash deposit of estimated CVDs for such entries of subject merchandise in the amounts indicated above. If the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated and all estimated duties deposited or securities posted as a result of the suspension of liquidation will be refunded or canceled.

International Trade Commission Notification

In accordance with section 705(d) of the Act, we will notify the ITC of our determination. In addition, we are making available to the ITC all non-privileged and non-proprietary information related to this investigation. We will allow the ITC access to all privileged and business proprietary information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under an administrative protective order (APO), without the written consent of the Assistant Secretary of Enforcement and Compliance.

Notification Regarding Administrative Protective Orders (APOs)

In the event the ITC issues a final negative injury determination, this notice will serve as the only reminder to parties subject to an APO of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation subject to sanction.

This determination and notice are issued and published pursuant to sections 705(d) and 777(i) of the Act and 19 CFR 351.210(c).

Dated: August 4, 2016.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix I—List of Topics Discussed in the Final Decision Memorandum

I. Summary
II. Background
III. Scope Comments
IV. Scope of the Investigation
V. Subsidies Valuation
VI. Benchmarks and Discount Rates
VII. Use of Facts Otherwise Available And Adverse Inferences
VIII. Analysis of Programs
IX. Analysis of Comments
  Comment 1: Whether the Department Should Apply Adverse Facts Available (AFA) to the Provision of Electricity for Less Than Adequate Remuneration (LTAR)
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  Comment 3: Whether the Department Should Use Other Bubmitted Data to Measure the Adequacy of Remuneration of Electricity
  Comment 4: Whether the Department Should Find the Provision of Natural Gas for LTAR Countervailable
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  Comment 6: Whether To Apply AFA to POSCO Global Research and Development (R&D) Center
  Comment 7: Whether To Apply AFA to Certain Loans Submitted at Verification
  Comment 8: Whether To Apply AFA to Hyundai Steel for Use of Certain Foreign Economic Zones (FEZs)
  Comment 9: The Department Improperly Countervailed Property Tax Exemptions Received by the Pohang Plant Under RSTA 78
  Comment 10: The Department's Methodology for Attributing RSTA Article 22 Benefits Received by Hyundai Corporation to Hyundai Steel Was Incorrect
  Comment 11: Whether Hyundai Steel Should Have Reported Additional ITIPA Grants
  Comment 12: Whether Hyundai Steel Should Have Provided a Questionnaire Response for Hyundai Green Power
X. Recommendation

Appendix II—Scope of the Investigation

The products covered by this investigation are certain hot-rolled, flat-rolled steel products, with or without patterns in relief, and whether or not annealed, painted, varnished, or coated with plastics or other non-metallic substances. The products covered do not include those that are clad, plated, or coated with metal. The products covered include coils that have a width or other lateral measurement ("width") of 12.7 mm or greater, regardless of thickness, and regardless of form of coil (*e.g.*, in successively superimposed layers, spirally oscillating, etc.). The products covered also include products not in coils (*e.g.*, in straight lengths) of a thickness of less than 4.75 mm and a width that is 12.7 mm or greater and that measures at least 10 times the thickness. The products described above may be rectangular, square, circular, or other shape and include products of either rectangular or non-rectangular cross-section where such cross-section is achieve subsequent to the rolling process, *i.e.*, products which have been "worked after rolling" (*e.g.*, products which have been beveled or rounded at the edges). For purposes of the width and thickness requirements referenced above:

(1) Where the nominal and actual measurements vary, a product is within the scope if application of either the nominal or actual measurement would place it within the scope based on the definitions set forth above unless the resulting measurement makes the product covered by the existing antidumping[5] or countervailing duty[6] orders on Certain Cut-To-Length Carbon-Quality Steel Plate Products From the Republic of Korea (A–580–836; C–580–837), and

(2) where the width and thickness vary for a specific product (*e.g.*, the thickness of certain products with non-rectangular cross-section, the width of certain products with non-rectangular shape, etc.), the measurement at its greatest width or thickness applies.

Steel products included in the scope of this investigation are products in which: (1) Iron predominates, by weight, over each of the other contained elements; (2) the carbon content is 2 percent or less, by weight; and (3) none of the elements listed below exceeds the quantity, by weight, respectively indicated:

- 2.50 percent of manganese, or
- 3.30 percent of silicon, or
- 1.50 percent of copper, or

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[5] *See Notice of Amendment of Final Determinations of Sales at Less Than Fair Value and Antidumping Duty Orders: Certain Cut-To-Length Carbon-Quality Steel Plate Products From France, India, Indonesia, Italy, Japan and the Republic of Korea*, 65 FR 6585 (February 10, 2000).

[6] *See Notice of Amended Final Determinations: Certain Cut-to-Length Carbon-Quality Steel Plate From India and the Republic of Korea; and Notice of Countervailing Duty Orders: Certain Cut-To-Length Carbon-Quality Steel Plate From France, India, Indonesia, Italy, and the Republic of Korea*, 65 FR 6587 (February 10, 2000).

- 1.50 percent of aluminum, or
- 1.25 percent of chromium, or
- 0.30 percent of cobalt, or
- 0.40 percent of lead, or
- 2.00 percent of nickel, or
- 0.30 percent of tungsten, or
- 0.80 percent of molybdenum, or
- 0.10 percent of niobium, or
- 0.30 percent of vanadium, or
- 0.30 percent of zirconium.

Unless specifically excluded, products are included in this scope regardless of levels of boron and titanium.

For example, specifically included in this scope are vacuum degassed, fully stabilized (commonly referred to as interstitial-free (IF)) steels, high strength low alloy (HSLA) steels, the substrate for motor lamination steels, Advanced High Strength Steels (AHSS), and Ultra High Strength Steels (UHSS). IF steels are recognized as low carbon steels with micro-alloying levels of elements such as titanium and/or niobium added to stabilize carbon and nitrogen elements. HSLA steels are recognized as steels with micro-alloying levels of elements such as chromium, copper, niobium, titanium, vanadium, and molybdenum. The substrate for motor lamination steels contains micro-alloying levels of elements such as silicon and aluminum. AHSS and UHSS are considered high tensile strength and high elongation steels, although AHSS and UHSS are covered whether or not they are high tensile strength or high elongation steels.

Subject merchandise includes hot-rolled steel that has been further processed in a third country, including but not limited to pickling, oiling, levelling, annealing, tempering, temper rolling, skin passing, painting, varnishing, trimming, cutting, punching, and/or slitting, or any other processing that would not otherwise remove the merchandise from the scope of the investigations if performed in the country of manufacture of the hot-rolled steel.

All products that meet the written physical description, and in which the chemistry quantities do not exceed any one of the noted element levels listed above, are within the scope of these investigations unless specifically excluded. The following products are outside of and/or specifically excluded from the scope of this investigation:

- Universal mill plates (*i.e.*, hot-rolled, flat-rolled products not in coils that have been rolled on four faces or in a closed box pass, of a width exceeding 150 mm but not exceeding 1250 mm, of a thickness not less than 4.0 mm, and without patterns in relief);
- Products that have been cold-rolled (cold-reduced) after hot-rolling;[7]
- Ball bearing steels;[8]
- Tool steels;[9] and
- Silico-manganese steels;[10]

The products subject to this investigation are currently classified in the Harmonized Tariff Schedule of the United States ("HTSUS") under item numbers: 7208.10.1500, 7208.10.3000, 7208.10.6000, 7208.25.3000, 7208.25.6000, 7208.26.0030, 7208.26.0060, 7208.27.0030, 7208.27.0060, 7208.36.0030, 7208.36.0060, 7208.37.0030, 7208.37.0060, 7208.38.0015, 7208.38.0030, 7208.38.0090, 7208.39.0015, 7208.39.0030, 7208.39.0090, 7208.40.6030, 7208.40.6060, 7208.53.0000, 7208.54.0000, 7208.90.0000, 7210.70.3000, 7211.14.0030, 7211.14.0090, 7211.19.1500, 7211.19.2000, 7211.19.3000, 7211.19.4500, 7211.19.6000, 7211.19.7530, 7211.19.7560, 7211.19.7590, 7225.11.0000, 7225.19.0000, 7225.30.3050, 7225.30.7000, 7225.40.7000, 7225.99.0090, 7226.11.1000, 7226.11.9030, 7226.11.9060, 7226.19.1000, 7226.19.9000, 7226.91.5000, 7226.91.7000, and 7226.91.8000. The products subject to the investigation may also enter under the following HTSUS numbers: 7210.90.9000, 7211.90.0000, 7212.40.1000, 7212.40.5000, 7212.50.0000, 7214.91.0015, 7214.91.0060, 7214.91.0090, 7214.99.0060, 7214.99.0075, 7214.99.0090, 7215.90.5000, 7226.99.0180, and 7228.60.6000.

The HTSUS subheadings above are provided for convenience and U.S. Customs purposes only. The written description of the scope of the investigation is dispositive.

[FR Doc. 2016–19377 Filed 8–11–16; 8:45 am]

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[7] For purposes of this scope exclusion, rolling operations such as a skin pass, levelling, temper rolling or other minor rolling operations after the hot-rolling process for purposes of surface finish, flatness, shape control, or gauge control do not constitute cold-rolling sufficient to meet this exclusion.

[8] Ball bearing steels are defined as steels which contain, in addition to iron, each of the following elements by weight in the amount specified: (i) Not less than 0.95 nor more than 1.13 percent of carbon; (ii) not less than 0.22 nor more than 0.48 percent of manganese; (iii) none, or not more than 0.03 percent of sulfur; (iv) none, or not more than 0.03 percent of phosphorus; (v) not less than 0.18 nor more than 0.37 percent of silicon; (vi) not less than 1.25 nor more than 1.65 percent of chromium; (vii) none, or not more than 0.28 percent of nickel; (viii) none, or not more than 0.38 percent of copper; and (ix) none, or not more than 0.09 percent of molybdenum.

[9] Tool steels are defined as steels which contain the following combinations of elements in the quantity by weight respectively indicated: (i) More than 1.2 percent carbon and more than 10.5 percent chromium; or (ii) not less than 0.3 percent carbon and 1.25 percent or more but less than 10.5 percent chromium; or (iii) not less than 0.85 percent carbon and 1 percent to 1.8 percent, inclusive, manganese; or (iv) 0.9 percent to 1.2 percent, inclusive, chromium and 0.9 percent to 1.4 percent, inclusive, molybdenum; or (v) not less than 0.5 percent carbon and not less than 3.5 percent molybdenum; or (vi) not less than 0.5 percent carbon and not less than 5.5 percent tungsten.

[10] Silico-manganese steel is defined as steels containing by weight: (i) Not more than 0.7 percent of carbon; (ii) 0.5 percent or more but not more than 1.9 percent of manganese, and (iii) 0.6 percent or more but not more than 2.3 percent of silicon.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–583–837]

Polyethylene Terephthalate Film, Sheet, and Strip From Taiwan: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2014–2015

AGENCY: Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce.

SUMMARY: The Department of Commerce (the Department) is conducting an administrative review of the antidumping duty order on polyethylene terephthalate film, sheet, and strip (PET Film) from Taiwan. The period of review (POR) is July 1, 2014, through June 30, 2015. This review covers respondents Nan Ya Plastics Corporation (Nan Ya) and Shinkong Materials Technology Corporation (SMTC), producers and exporters of PET Film from Taiwan. The Department preliminarily determines that sales of subject merchandise have not been made below normal value (NV) by Nan Ya, and that SMTC had no shipments during the POR. Interested parties are invited to comment on these preliminary results.

DATES: Effective August 12, 2016.

FOR FURTHER INFORMATION CONTACT: Jacqueline Arrowsmith at (202) 482–5255; AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Scope of the Order

The merchandise subject to the order is PET Film. The PET Film subject to the order is currently classifiable under subheading 3920.62.00.90 of the Harmonized Tariff Schedule of the United States.[1] The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty

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[1] A full description of the scope of the order is contained in the memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Ronald K. Lorentzen, Acting Assistant Secretary for Enforcement and Compliance, "Decision Memorandum for Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments: Polyethylene Terephthalate Film, Sheet, and Strip from Taiwan; 2014–2015" (Preliminary Decision Memorandum), which is hereby adopted by this notice.

Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov* and is available to all parties in the Central Records Unit in room B8024 of the main Commerce building. In addition, a complete version of the Decision Memorandum can be accessed directly on the Internet at *http://enforcement.trade.gov/frn/index.html.* The signed and electronic versions of the Decision Memorandum are identical in content.

Methodology

The Department is conducting this review in accordance with section 751(a)(2) of the Tariff Act of 1930, as amended (the Act). Export price is calculated in accordance with section 772 of the Act. NV is calculated in accordance with section 773 of the Act.

For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum.

Preliminary Determination of No Shipments

Based on our analysis of U.S. Customs and Border Protection (CBP) information and information provided by SMTC,[2] we preliminarily determine that SMTC had no shipments of the subject merchandise, and, therefore, no reviewable transactions, during the POR.

Preliminary Results of Review

As a result of this review, we preliminarily determine the following weighted-average dumping margin for the period July 1, 2014, through June 30, 2015.

Manufacturer/exporter	Weighted-average dumping margin (percent)
Nan Ya Plastics Corporation	0.00

Disclosure and Public Comment

The Department intends to disclose to interested parties the calculations performed in connection with these preliminary results within five days of the date of publication of this notice.[3] Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs no later than 30 days after the date of publication of this notice.[4] Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[5] Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[6] Case and rebuttal briefs should be filed using ACCESS.[7] In order to be properly filed, ACCESS must successfully receive an electronically-filed document in its entirety by 5 p.m. Eastern Time.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS, within 30 days after the date of publication of this notice.[8] Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs.

Unless extended, the Department intends to issue the final results of this administrative review, including the results of its analysis of the issues raised in any written briefs, not later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h).

Assessment Rates

Upon completion of the administrative review, the Department shall determine, and CBP shall assess, antidumping duties on all appropriate entries in accordance with 19 CFR 351.212(b)(1). If Nan Ya's weighted-average dumping margin is not zero or *de minimis* (*i.e.,* less than 0.5 percent) in the final results of this review, we will calculate importer-specific assessment rates on the basis of the ratio of the total amount of dumping calculated for the importer's examined sales and the total entered value of the sales in accordance with 19 CFR 351.212(b)(1). We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review when the importer-specific assessment rate calculated in the final results of this review is above *de minimis.* Where the respondent's weighted-average dumping margin is zero or *de minimis,* or an importer-specific assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties. The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.

Consistent with the Department's "automatic assessment" regulation for entries this clarification will apply to entries of subject merchandise during the POR produced by Nan Ya for which it did not know that its merchandise was destined for the United States.[9] Furthermore, this clarification applies to all POR entries entered under the case number for SMTC if we continue to make a final determination of no shipments of subject merchandise because it certified that it made no POR shipments of subject merchandise for which it had knowledge of the U.S. destination. In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate of 2.40 percent[10] if there is no rate for the intermediary company(ies) involved in the transaction.[11]

We intend to issue instructions to CBP 15 days after the date of publication of the final results of this review.

Cash Deposit Requirements

The following deposit requirements will be effective for all shipments of PET Film from Taiwan entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review, as provided for by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for the company under review will be the rate established in the final results of this review (except, if the rate is zero or *de minimis,* no cash deposit will be required); (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the less-than-fair-value investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters is 2.40 percent.[12] These cash deposit requirements, when imposed, shall remain in effect until further notice.

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[2] In the *Preliminary Results* for the 2008–2009 antidumping duty administrative review, we determined that for the purposes of calculating an antidumping margin, SMTC, and its parent company Shinkong Synthetic Fibers Corporation (SSFC), should be treated as a single entity. *See Polyethylene Terephthalate Film, Sheet and Strip from Taiwan: Preliminary Results of Antidumping Duty Administrative Review,* 75 FR 49902 (August 16, 2010), (unchanged in the *Final Results* for the 2008–2009 antidumping duty administrative review (*Polyethylene Terephthalate Film, Sheet and Strip from Taiwan: Final Results of Antidumping Duty Administrative Review,* 76 FR 9745 (February 22, 2011))).

[3] *See* 19 CFR 351.224(b).

[4] *See* 19 CFR 351.309(c)(ii).

[5] *See* 19 CFR 351.309(d).

[6] *See* 19 CFR 351.309(c)(2) and (d)(2).

[7] *See* 19 CFR 351.303.

[8] *See* 19 CFR 351.310(c).

[9] *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,*68 FR 23954 (May 6, 2003) (*Assessment Policy Notice*). *See also Brass Sheet and Strip From Germany: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2013–2014,* 80 FR 61369 (October 13, 2015).

[10] *See Notice of Amended Final Antidumping Duty Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Polyethylene Terephthalate Film, Sheet, and Strip (PET Film) from Taiwan,* 67 FR 44174. (July 1, 2002), as amended in 67 FR 46566 (July 15, 2002) (*PET Film from Taiwan Amended Final Determination*).

[11] For a full discussion of this clarification, *see Assessment Policy Notice.*

Notification to Interested Parties

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213(h)(1).

Dated: August 5, 2016.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Preliminary Decision Memorandum

1. Summary
2. Background
3. Scope of the Order
4. Preliminary Finding of No Shipments for SMTC
5. Comparisons to Normal Value
6. Product Comparisons
7. Date of Sale
8. Export Price
9. Normal Value
10. Currency Conversion
11. Recommendation

[FR Doc. 2016–19136 Filed 8–11–16; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE451

Takes of Marine Mammals Incidental to Specified Activities; Marine Geophysical Survey in the Southeast Pacific Ocean, 2016–2017

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce.

ACTION: Notice; issuance of an incidental harassment authorization.

SUMMARY: In accordance with the regulations implementing the Marine Mammal Protection Act (MMPA) as amended, notification is hereby given that NMFS has issued an incidental harassment authorization (IHA) to Lamont-Doherty Earth Observatory (Lamont-Doherty) in collaboration with the National Science Foundation (NSF), to incidentally take, by level B harassment, 44 species of marine mammals, and to incidentally take, by Level A harassment, 26 species of marine mammals, during three marine geophysical (seismic) surveys in the southeast Pacific Ocean.

DATES: This Authorization is effective from August 1, 2016, through July 31, 2017.

FOR FURTHER INFORMATION CONTACT: Jordan Carduner, NMFS, Office of Protected Resources, NMFS (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

Section 101(a)(5)(D) of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*) directs the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals of a species or population stock, by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if, after NMFS provides a notice of a proposed authorization to the public for review and comment: (1) NMFS makes certain findings; and (2) the taking is limited to harassment.

An Authorization shall be granted for the incidental taking of small numbers of marine mammals if NMFS finds that the taking will have a negligible impact on the species or stock(s), and will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant). The Authorization must also set forth the permissible methods of taking; other means of effecting the least practicable adverse impact on the species or stock and its habitat (*i.e.,* mitigation); and requirements pertaining to the monitoring and reporting of such taking. NMFS has defined "negligible impact" in 50 CFR 216.103 as "an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival."

Except with respect to certain activities not pertinent here, the MMPA defines "harassment" as: Any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment].

Summary of Request

On January 19, 2016, NMFS received an application from Lamont-Doherty requesting that NMFS issue an Authorization for the take of marine mammals, incidental to Oregon State University (OSU) and University of Texas (UT) conducting seismic surveys in the southeast Pacific Ocean, in the latter half of 2016 and/or the first half of 2017. NMFS considered the application and supporting materials adequate and complete on March 21, 2016.

Lamont-Doherty plans to conduct three two-dimensional (2-D) surveys on the R/V *Marcus G. Langseth* (*Langseth*), a vessel owned by NSF and operated on its behalf by Columbia University's Lamont-Doherty Earth Observatory primarily in international waters of the southeast Pacific Ocean, with a small portion of the surveys occurring within the territorial waters of Chile, which extend to nautical 12 miles (mi) (19.3 kilometers (km)) from the coast. NMFS cannot authorize the incidental take of marine mammals in the territorial seas of foreign nations, as the MMPA does not apply in those waters. However, as part of the analysis supporting our determination under the MMPA that the activity would have a negligible impact on the affected species, we must consider the level of incidental take as a result of the activity in the entire activity area (including both territorial seas and high seas).

Increased underwater sound generated during the operation of the seismic airgun array is the only aspect of the activity that is likely to result in the take of marine mammals. We anticipate that take, by Level B harassment, of 44 species of marine mammals could result from the specified activity. Although unlikely, NMFS also anticipates that a small amount of take by Level A harassment of 26 species of marine mammals could occur during the planned surveys.

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[12] *See PET Film from Taiwan Amended Final Determination.*

Description of the Specified Activity

Lamont-Doherty plans to use one source vessel, the *Langseth*, with an array of 36 airguns as the energy source with a total volume of approximately 6,600 cubic inches (in^3). The receiving system would consist of up to 64 ocean bottom seismometers and a single hydrophone streamer between 8 and 15 km (4.9 and 9.3 mi) in length. In addition to the operations of the airgun array, a multibeam echosounder (MBES) and a sub-bottom profiler (SBP) would also be operated continuously throughout the proposed surveys. A total of approximately 9,633 km (5,986 mi) of transect lines would be surveyed in the southeast Pacific Ocean.

A detailed description of Lamont-Doherty's planned seismic surveys is provided in the **Federal Register** notice for the proposed IHA (81 FR 23117; April 19, 2016). Since that time, no changes have been made to the planned activities. Therefore, a detailed description is not provided here. Please refer to that **Federal Register** notice for the description of the specific activity.

Comments and Responses

NMFS published a notice of receipt of Lamont-Doherty's application and proposed Authorization in the **Federal Register** on April 19, 2016 (81 FR 23117). During the 30-day public comment period, NMFS received comment letters from the Marine Mammal Commission (Commission) and from the Marcus Langseth Science Oversight Committee, as well as one comment from a member of the general public. NMFS has posted the comments online at: *http://www.nmfs.noaa.gov/pr/permits/incidental*.

NMFS addresses any comments specific to Lamont-Doherty's application related to the statutory and regulatory requirements or findings that NMFS must make under the MMPA in order to issue an Authorization. The following is a summary of the public comments and NMFS's responses.

Modeling Exclusion and Buffer Zones

Comment 1: The Commission expressed concerns regarding Lamont-Doherty's method to estimate exclusion and buffer zones. The Commission stated that the model is not the best available science because it assumes the following: Spherical spreading, constant sound speed, and no bottom interactions for surveys in deep water. In light of their concerns, the Commission recommended that NMFS require Lamont-Doherty to re-estimate the exclusion and buffer zones incorporating site-specific environmental (including sound speed profiles, bathymetry, and sediment characteristics) and operational (including number/type/spacing of airguns, tow depth, source level/operating pressure, and operational volume) parameters into their model.

Response: NMFS acknowledges the Commission's concerns about Lamont-Doherty's current modeling approach for estimating exclusion and buffer zones and also acknowledges that Lamont-Doherty did not incorporate site-specific sound speed profiles, bathymetry, and sediment characteristics of the research area in the current approach to estimate those zones for this planned seismic survey.

Lamont-Doherty's application (LGL, 2016) and the NSF's draft environmental analysis (NSF, 2016) describe the approach to establishing mitigation exclusion and buffer zones. In summary, Lamont-Doherty acquired field measurements for several array configurations at shallow, intermediate, and deep-water depths during acoustic verification studies conducted in the northern Gulf of Mexico in 2007 and 2008 (Tolstoy *et al.*, 2009). Based on the empirical data from those studies, Lamont-Doherty developed a sound propagation modeling approach that predicts received sound levels as a function of distance from a particular airgun array configuration in deep water. For this survey, Lamont-Doherty developed the exclusion and buffer zones for the airgun array based on the empirically-derived measurements from the Gulf of Mexico calibration survey (Appendix H of NSF's 2011 PEIS). For deep water (≤1000 m), Lamont-Doherty used the deep-water radii obtained from model results down to a maximum water depth of 2000 m (Figure 2 and 3 in Appendix H of NSF's 2011 PEIS; the radii for intermediate water depths (100–1000 m) were derived from the deep-water ones by applying a correction factor (multiplication) of 1.5, such that observed levels at very near offsets fall below the corrected mitigation curve (Fig. 16 in Appendix H of the NSF's 2011 PEIS); the shallow-water radii were obtained by scaling the empirically derived measurements from the Gulf of Mexico calibration survey to account for the differences in tow depth between the calibration survey (6 m) and the proposed surveys (9 and 12 m).

In 2015, Lamont-Doherty explored the question of whether the Gulf of Mexico calibration data adequately informs the model to predict exclusion isopleths in other areas by conducting a retrospective sound power analysis of one of the lines acquired during Lamont-Doherty's seismic survey offshore New Jersey in 2014 (Crone, 2015). NMFS presented a comparison of the predicted radii (*i.e.*, modeled exclusion zones) with radii based on in situ measurements (*i.e.*, the upper bound [95th percentile] of the cross-line prediction) in a previous notice of issued Authorization for Lamont-Doherty (see Table 1, 80 FR 27635, May 14, 2015).

Briefly, Crone's (2015) analysis, specific to the survey site offshore New Jersey, confirmed that in-situ, site specific measurements and estimates of the 160- and 180-dB isopleths collected by the *Langseth's* hydrophone streamer in shallow water were smaller than the modeled (*i.e.*, predicted) exclusion and buffer zones proposed for use in two seismic surveys conducted offshore New Jersey in shallow water in 2014 and 2015. In that particular case, Crone's (2015) results showed that Lamont-Doherty's modeled exclusion (180-dB) and buffer (160-dB) zones were approximately 28 and 33 percent smaller, respectively, than the in situ, site-specific measurements, thus confirming that Lamont-Doherty's model was conservative in that case, as emphasized by Lamont-Doherty in its application and in supporting environmental documentation. The following is a summary of two additional analyses of in-situ data that support Lamont-Doherty's use of the modeled exclusion and buffer zones in this particular case.

In 2010, Lamont-Doherty assessed the accuracy of their modeling approach by comparing the sound levels of the field measurements acquired in the Gulf of Mexico study to their model predictions (Diebold *et al.*, 2010). They reported that the observed sound levels from the field measurements fell almost entirely below the predicted mitigation radii curve for deep water (greater than 1,000 m; 3280.8 ft) (Diebold *et al.*, 2010).

In 2012, Lamont-Doherty used a similar process to model exclusion and buffer zones for a shallow-water seismic survey in the northeast Pacific Ocean offshore Washington State in 2012. Lamont-Doherty conducted the shallow-water survey using the same airgun configuration planned for this seismic survey (*i.e.*, 6,600 in^3) and recorded the received sound levels on both the shelf and slope off Washington State using the *Langseth's* 8 km hydrophone streamer. Crone *et al.* (2014) analyzed those received sound levels from the 2012 survey and confirmed that in-situ, site specific measurements and estimates of the 160-dB and 180-dB isopleths collected by the *Langseth's* hydrophone streamer in shallow water were two to three times smaller than Lamont-Doherty's modeling approach had predicted. While the results confirmed bathymetry's role in sound propagation, Crone *et al.* (2014) were able to confirm that the empirical measurements from the Gulf of Mexico calibration survey (the same measurements used to inform Lamont-Doherty's modeling approach for the planned seismic survey in the southeast Pacific Ocean) overestimated the size of the exclusion and buffer zones for the shallow-water 2012 survey off Washington State and were thus precautionary, in that particular case.

The model Lamont-Doherty currently uses does not allow for the consideration of environmental and site-specific parameters as requested by the Commission. NMFS continues to work with Lamont-Doherty and the NSF to address the issue of incorporating site-specific information to further inform the analysis and development of mitigation measures in oceanic and coastal areas for future seismic surveys with Lamont-Doherty. However, Lamont-Doherty's current modeling approach (supported by the three data points discussed previously) represents the best available information for NMFS to reach determinations for the Authorization. As described earlier, the comparisons of Lamont-Doherty's model results and the field data collected in the Gulf of Mexico, offshore Washington State, and offshore New Jersey illustrate a degree of conservativeness built into Lamont-Doherty's model for deep water, which NMFS expects to offset some of the limitations of the model to capture the variability resulting from site-specific factors. Based upon the best available information (*i.e.,* the three data points, two of which are peer-reviewed, discussed in this response), NMFS finds that the exclusion and buffer zone calculations are appropriate for use in this particular survey.

Lamont-Doherty has conveyed to NMFS that additional modeling efforts to refine the process and conduct comparative analysis may be possible with the availability of research funds and other resources. Obtaining research funds is typically accomplished through a competitive process, including those submitted to U.S. Federal agencies. The use of models for calculating buffer and exclusion zone radii and for developing take estimates is not a requirement of the MMPA incidental take authorization process. Furthermore, NMFS does not provide specific guidance on model parameters nor prescribe a specific model for applicants as part of the MMPA incidental take authorization process at this time. There is a level of variability not only with parameters in the models, but also the uncertainty associated with data used in models, and therefore, the quality of the model results submitted by applicants. NMFS considers this variability when evaluating applications and the take estimates and mitigation measures that the model informs. NMFS takes into consideration the model used, and its results, in determining the potential impacts to marine mammals; however, it is just one component of the analysis during the MMPA authorization process as NMFS also takes into consideration other factors associated with the activity (*e.g.,* geographic location, duration of activities, context, sound source intensity, etc.).

Uncertainty in Density Estimates

Comment 2: The Commission expressed concern regarding uncertainty in the representativeness of the marine mammal density data and the assumptions used to calculate estimated takes. The Commission recommended that NMFS adjust density estimates using some measure of uncertainty when available density data originate from different geographic areas, temporal scales, and seasons, especially for actions which will occur outside the U.S. Exclusive Economic Zone (EEZ) where site- and species-specific density estimates tend to be scant, such as Lamont-Doherty's planned survey.

Response: NMFS believes that, in the absence of site-specific marine mammal density data in the region of Lamont-Doherty's planned survey, the best available information was used to estimate marine mammal density data for the project area and to calculate estimated takes. However, NMFS acknowledges that the lack of site- and species-specific density data for certain geographic areas presents inherent challenges in estimating takes, and agrees with the Commission's recommendation that a systematic approach to incorporating uncertainty in density estimates when available density data originate from different geographic areas, temporal scales, and seasons is warranted. NMFS is actively working to develop a systematic process for the use of density estimates in authorizations when uncertainties in density data exist as a result of geographic differences, temporal differences, or accuracy of data, and to encourage applicants for incidental take authorization to utilize this process when it is complete. NMFS looks forward to developing this process in collaboration with the Commission.

Monitoring and Reporting

Comment 3: The Commission indicated that monitoring and reporting requirements should provide a reasonably accurate assessment of the types of taking and the numbers of animals taken by the proposed activity. They recommend that NMFS and Lamont-Doherty incorporate an accounting for animals at the surface but not detected [*i.e.,* g(0) values] and for animals present but underwater and not available for sighting [*i.e.,* f(0) values] into monitoring efforts. In light of the Commission's previous comments, they recommend that NMFS consult with the funding agency (*i.e.,* the NSF) and individual applicants (*e.g.,* Lamont-Doherty and other related entities) to develop, validate, and implement a monitoring program that provides a scientifically sound, reasonably accurate assessment of the types of marine mammal takes and the actual numbers of marine mammals taken, accounting for applicable g(0) and f(0) values, based in part on monitoring data collected during geophysical surveys.

Response: NMFS agrees with the Commission's recommendation to improve the post-survey reporting requirements for NSF and Lamont-Doherty by accounting for takes using applicable g(0) and f(0) values. In December 2015, NMFS met with Commission representatives to discuss ways to develop and validate a monitoring program that provides a scientifically sound, reasonably accurate assessment of the types of marine mammal takes and the actual numbers of marine mammals taken. In July 2016, NMFS solicited input from the Commission regarding methodology for determining applicable g(0) and f(0) values. Based on this input, NMFS has included a requirement in the issued IHA that Lamont-Doherty must provide an estimate of the number (by species) of marine mammals that may have been exposed (based on modeling results and accounting for animals at the surface but not detected [*i.e.,* g(0) values] and for animals present but underwater and not available for sighting [*i.e.,* f(0) values]) to the seismic activity at received levels greater than or equal to 160 dB re: 1 μPa and/or 180 dB re 1 μPa for cetaceans and 190-dB re 1 μPa for pinnipeds. NMFS will provide the methodology for determining the applicable f(0) and g(0) values to Lamont-Doherty.

The comment letter from the Marcus Langseth Science Oversight Committee affirmed that there is significant support from the Committee for the IHA to be issued for the proposed activity and for the survey to be conducted. NMFS received one additional comment from a private citizen that expressed concern that the project would result in the deaths of marine mammals and that the application should be denied on the grounds that it would cost taxpayers too much money; NMFS considered this comment, however, no deaths of marine mammals are anticipated as a result of the project as described below, and NMFS does not have the ability to deny applications for authorization to incidentally take marine mammals based on an applicant's funding sources.

Description of Marine Mammals in the Area of the Specified Activity

Table 1 in this notice provides the following: All marine mammal species with possible or confirmed occurrence in the planned activity area; information on those species' regulatory status under the MMPA and the Endangered Species Act of 1973 (16 U.S.C. 1531 *et seq.*); abundance; local occurrence and range; and seasonality in the planned activity area. Based on the best available information, NMFS expects that there may be a potential for certain cetacean and pinniped species to occur within the survey area (*i.e.,* potentially be taken) and have included additional information for these species in Table 1 of this notice. NMFS will carry forward analyses on the species listed in Table 1 later in this document.

Table 1—General Information on Marine Mammals That Could Potentially Occur in the Three Planned Survey Areas Within the Southeast Pacific Ocean

Species	Regulatory status[1][2]	Species abundance[3]	Local occurrence	Habitat
Antarctic minke whale (*Balaenoptera bonaerensis*).	MMPA—NC; ESA—NL	515,000	North—Rare; Central/South—Uncommon.	Coastal, pelagic.
Blue whale (*B. musculus*)	MMPA—D; ESA—EN	[4] 10,000	North—Common; Central/South—Common.	Coastal, shelf, pelagic.
Bryde's whale (*Balaenoptera edeni*)	MMPA—NC; ESA—NL	[5] 43,633	North—Common; Central/South—Common.	Coastal, pelagic.
Common minke whale (*B. acutorostrata*)	MMPA—NC; ESA—NL	515,000	North—Rare; Central/South—Uncommon.	Coastal, pelagic.
Fin whale (*B. physalus*)	MMPA—D; ESA—EN	22,000	North—Rare; Central/South—Common.	Shelf, slope, pelagic.
Humpback whale (*Megaptera novaeangliae*)	MMPA—D; ESA—EN	42,000	North—Common; Central/South—Common.	Coastal, shelf, pelagic.
Pygmy right whale (*Caperea marginata*)	MMPA—NC; ESA—NL	Unknown	North—Unknown; Central/South—Rare.	Coastal, oceanic.
Sei whale (*B. borealis*)	MMPA—D; ESA—EN	10,000	North—Uncommon; Central/South—Uncommon.	Pelagic.
Southern right whale (*Eubalaena australis*)	MMPA—D; ESA—EN	12,000	North—Rare; Central/South—Rare.	Coastal, oceanic.
Sperm whale (*Physeter macrocephalus*)	MMPA—D; ESA—EN	[6] 355,000	North—Common; Central/South—Common.	Pelagic, deep seas.
Dwarf sperm whale (*Kogia sima*)	MMPA—NC; ESA—NL	[7] 170,309	North—Rare; Central/South—Rare.	Shelf, pelagic.
Pygmy sperm whale (*K. breviceps*)	MMPA—NC; ESA—NL	[7] 170,309	North—Rare; Central/South—Rare.	Shelf, pelagic.
Andrew's beaked whale (*Mesoplodon bowdoini*)	MMPA—NC; ESA—NL	[8] 25,300	North—Unknown; Central/South—Rare.	Pelagic.
Blainville's beaked whale (*M. densirostris*)	MMPA—NC; ESA—NL	[8] 25,300	North—Uncommon; Central/South—Uncommon.	Pelagic.
Cuvier's beaked whale (*Ziphius cavirostris*)	MMPA—NC; ESA—NL	[8] 20,000	North—Uncommon; Central/South—Uncommon.	Slope, pelagic.
Gray's beaked whale (*M. grayi*)	MMPA—NC; ESA—NL	[8] 25,300	North—Rare; Central/South—Rare.	Pelagic.
Hector's beaked whale (*M. hectori*)	MMPA—NC; ESA—NL	[8] 25,300	North—Unknown; Central/South—Rare.	Pelagic.
Pygmy beaked whale (*Mesoplodon peruvianus*)	MMPA—NC; ESA—NL	[8] 25,300	North—Rare; Central/South—Rare.	Pelagic.
Shepherd's beaked whale (*Tasmacetus shepherdi*).	MMPA—NC; ESA—NL	[8] 25,300	North—Unknown; Central/South—Rare.	Pelagic.
Spade-toothed whale (*Mesoplodon traversii*)	MMPA—NC; ESA—NL	[8] 25,300	North—Unknown; Central/South—Rare.	Pelagic.
Strap-toothed beaked whale (*M. layardii*)	MMPA—NC; ESA—NL	[8] 25,300	North—Unknown; Central/South—Rare.	Pelagic.
Southern bottlenose whale (*Hyperoodon planifrons*).	MMPA—NC; ESA—NL	[9] 72,000	North—Unknown; Central/South—Uncommon.	Pelagic.
Chilean dolphin (*Cephalorhynchus eutropia*)	MMPA—NC; ESA—NL	10,000	North—Unknown; Central/South—Uncommon.	Coastal.

TABLE 1—GENERAL INFORMATION ON MARINE MAMMALS THAT COULD POTENTIALLY OCCUR IN THE THREE PLANNED SURVEY AREAS WITHIN THE SOUTHEAST PACIFIC OCEAN—Continued

Species	Regulatory status [1,2]	Species abundance [3]	Local occurrence	Habitat
Rough-toothed dolphin (*Steno bredanensis*)	MMPA—NC; ESA—NL	[10] 107,633	North—Rare; Central/South—Unknown.	Oceanic.
Common bottlenose dolphin (*Tursiops truncatus*)	MMPA—NC; ESA—NL	[10] 335,834	North—Abundant; Central/South—Common.	Coastal, pelagic, shelf.
Striped dolphin (*S. coeruleoalba*)	MMPA—NC; ESA—NL	[10] 964,362	North—Abundant; Central/South—Common.	Shelf edge, pelagic.
Short-beaked common dolphin (*Delphinus delphis*).	MMPA—NC; ESA—NL	[11] 1,766,551	North—Abundant; Central/South—Abundant.	Coastal, shelf.
Long-beaked common dolphin (*Delphinus capensis*).	MMPA—NC; ESA—NL	[12] 144,000	North—Uncommon; Central/South—Unknown.	Coastal, shelf.
Dusky dolphin (*Lagenorhynchus obscurus*)	MMPA—NC; ESA—NL	[13] 25,880	North—Abundant; Central/South—Abundant.	Shelf, slope.
Peale's dolphin (*Lagenorhynchus australis*)	MMPA—NC; ESA—NL	Unknown	North—Unknown; Central/South—Uncommon.	Coastal.
Hourglass dolphin (*Lagenorhynchus cruciger*)	MMPA—NC; ESA—NL	[14] 144,300	North—Unknown; Central/South—Rare.	Pelagic.
Southern right whale dolphin (*Lissodelphis peronii*).	MMPA—NC; ESA—NL	Unknown	North—Uncommon; Central/South—Common.	Pelagic.
Risso's dolphin (*Grampus griseus*)	MMPA—NC; ESA—NL	[10] 110,457	North—Common; Central/South—Uncommon.	Shelf, slope.
Pygmy killer whale (*Feresa attenuate*)	MMPA—NC; ESA—NL	[8] 38,900	North—Rare; Central/South—Uncommon.	Oceanic, pantropical.
False killer whale (*Pseudorca crassidens*)	MMPA—NC; ESA—NL	[8] 39,800	North—Uncommon; Central/South—Rare.	Pelagic.
Killer whale (*Orcinus orca*)	MMPA—NC; ESA—NL	50,000	North—Rare; Central/South—Rare.	Coastal, shelf, pelagic.
Long-finned pilot whale (*Globicephala melas*)	MMPA—NC; ESA—NL	[15] 200,000	North—Rare; Central/South—Rare.	Coastal, pelagic.
Short-finned pilot whale (*Globicephala macrorhynchus*).	MMPA—NC; ESA—NL	[16] 589,315	North—Rare; Central/South—Rare.	Coastal, pelagic.
Burmeister's porpoise (*Phocoena spinipinnis*)	MMPA—NC; ESA—NL	Unknown	North—Coastal; Central/South—Coastal.	Coastal.
Juan Fernandez fur seal (*Arctocephalus philippii*).	MMPA—NC; ESA—NL	[17] 32,278	North—Rare; Central/South—Rare.	Coastal, pelagic.
South American fur seal (*Arctocephalus australis*).	MMPA—NC; ESA—NL	250,000	North—Rare; Central/South—Rare.	Coastal, shelf, slope.
South American sea lion (*Otaria byronia*)	MMPA—NC; ESA—NL	[18] 397,771	North—Abundant; Central/South—Abundant.	Coastal, shelf.
Southern elephant seal (*Mirounga leonina*)	MMPA—NC; ESA—NL	[19] 640,000	North—Abundant; Central/South—Abundant.	Coastal, pelagic.

[1] MMPA: NC. = Not classified; D= Depleted.

[2] ESA: EN = Endangered, T = Threatened, DL = Delisted, NL = Not listed.

[3] Except where noted best estimate abundance information obtained from the International Whaling Commission's whale population estimates (IWC, 2016) or from the International Union for Conservation of Nature and Natural Resources Red List of Threatened Species Web site (IUCN, 2016). Unknown = Abundance information does not exist for this species.

[4] IUCN's best estimate of the global population is 10,000 to 25,000.

[5] Estimate from IUCN's Web page for Bryde's whales. Southern Hemisphere: southern Indian Ocean (13,854); western South Pacific (16,585); and eastern South Pacific (13,194) (IWC, 1981).

[6] Whitehead (2002).

[7] Estimate from IUCN's Web page for *Kogia* spp. Eastern Tropical Pacific (ETP) (150,000); Hawaii (19,172); Gulf of Mexico (742); and western Atlantic (395).

[8] Wade and Gerrodette (1993).

[9] South of 60°S from the 1885/1986–1990/1991 IWC/IDCR and SOWER surveys (Branch and Butterworth, 2001).

[10] ETP, line-transect survey, August-December 2006 (Gerrodette *et al.*, 2008).

[11] ETP, southern stock, 2000 survey (Gerrodette and Forcada 2002).

[12] Gerrodette and Palacios (1996) estimated 55,000 within Pacific coast waters of Mexico, 69,000 in the Gulf of California, and 20,000 off South Africa. IUCN, 2016.

[13] IUCN, 2016 and Markowitz, 2004.

[14] Kasamatsu and Joyce, 1995.

[15] Abundance estimates for beaked, southern bottlenose, and pilot whales south of the Antarctic Convergence in January (Kasamatsu and Joyce, 1995).

[16] Gerrodette and Forcada (2002).

[17] 2005/2006 minimum population estimate (Osman, 2008).

[18] Crespo *et al.* (2012). Current status of the South American sea lion along the distribution range.

[19] Hindell and Perrin (2009).

NMFS refers the public to Lamont-Doherty's application and NSF's environmental analysis (available online at: *http://www.nmfs.noaa.gov/pr/sars/species.htm*) for further information on the biology and local distribution of these species. Please also refer to NMFS's Web site (*http://www.nmfs.noaa.gov/pr/permits/incidental/*) for generalized species accounts.

Potential Effects of the Specified Activities on Marine Mammals

Operating active acoustic sources, such as airgun arrays, has the potential for adverse effects on marine mammals. The **Federal Register** notice for the proposed IHA (81 FR 23117; April 19, 2016) provided a discussion of the effects of anthropogenic noise on marine mammals as well as a detailed description of the potential effects of Lamont-Doherty's activities on marine mammals. Therefore that information is not repeated here; please refer to the **Federal Register** notice for the proposed IHA (81 FR 23117; April 19, 2016) for that information. During 10 nm of transit that may occur between surveys (described in the **Federal Register** notice for the proposed IHA (81 FR 23117; April 19, 2016)) the operation of the MBES and SBP may occur independent of airgun operation. The operation of the MBES and SBP in the absence of airgun use was not explicitly described in the **Federal Register** notice for the proposed IHA (81 FR 23117; April 19, 2016); though it comprises a very small portion of the total anticipated effects of this action, it has now been included for consideration in the analyses. The "Estimated Take by Incidental Harassment" section later in this document will include a quantitative analysis of the number of individuals that NMFS expects to be taken by this activity. The "Negligible Impact Analysis" section will include the analysis of how this specific activity would impact marine mammals and will consider the content of this section, the "Estimated Take by Incidental Harassment" section, the "Mitigation Measures" section, and the "Anticipated Effects on Marine Mammal Habitat" section to draw conclusions regarding the likely impacts of this activity on the reproductive success or survivorship of individuals and from that on the affected marine mammal populations or stocks.

Anticipated Effects on Marine Mammal Habitat

The primary potential impacts to marine mammal habitat and other marine species from Lamont-Doherty's planned activities are associated with elevated sound levels produced by airguns. The impacts of Lamont-Doherty's planned activities on fish and other marine life specifically related to acoustic activities are expected to be temporary in nature, negligible, and would not result in substantial impact to these species or to their role in the ecosystem. NMFS does not anticipate that the planned activity would have any habitat-related effects that could cause significant or long-term consequences for individual marine mammals or their populations. The potential effects of Lamont-Doherty's planned activities on marine mammal habitat and other marine species are discussed in detail in the **Federal Register** notice for the proposed IHA (81 FR 23117; April 19, 2016), therefore that information is not repeated here; please refer to that **Federal Register** notice for that information.

Mitigation Measures

In order to issue an Incidental Harassment Authorization under section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable adverse impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for taking for certain subsistence uses (where relevant).

Lamont-Doherty has reviewed the following source documents and has incorporated a suite of mitigation measures into their project description:

(1) Protocols used during previous Lamont-Doherty and NSF-funded seismic research cruises as approved by us and detailed in the NSF's 2011 PEIS and 2016 draft environmental analysis;

(2) Previous IHA applications and authorizations that NMFS has approved and authorized; and

(3) Recommended best practices in Richardson *et al.* (1995), Pierson *et al.* (1998), and Weir and Dolman (2007).

To reduce the potential for disturbance from acoustic stimuli associated with the activities, Lamont-Doherty, and/or its designees plan to implement the following mitigation measures for marine mammals:

(1) Vessel-based visual mitigation monitoring;
(2) Exclusion zones;
(3) Power down procedures;
(4) Shutdown procedures;
(5) Ramp-up procedures; and
(6) Speed and course alterations.

NMFS reviewed Lamont-Doherty's mitigation measures and developed the following additional mitigation measures to effect the least practicable adverse impact on marine mammals:

(1) Expanded power down procedures for concentrations of six or more whales that do not appear to be traveling (*e.g.*, feeding, socializing, etc.).

Vessel-Based Visual Mitigation Monitoring

Lamont-Doherty would position observers aboard the seismic source vessel to watch for marine mammals near the vessel during daytime airgun operations and during any start-ups at night. Observers would also watch for marine mammals near the seismic vessel for at least 30 minutes prior to the start of airgun operations after an extended shutdown (*i.e.*, greater than approximately eight minutes for this planned cruise). When feasible, the observers would conduct observations during daytime periods when the seismic system is not operating for comparison of sighting rates and behavior with and without airgun operations and between acquisition periods. Based on the observations, the *Langseth* would power down or shutdown the airguns when marine mammals are observed within or about to enter a designated exclusion zone for cetaceans or pinnipeds.

During seismic operations, at least four protected species observers would be aboard the *Langseth*. Lamont-Doherty would appoint the observers with NMFS's concurrence, and they would conduct observations during ongoing daytime operations and nighttime ramp-ups of the airgun array. During the majority of seismic operations, two observers would be on duty from the observation tower to monitor marine mammals near the seismic vessel. Using two observers would increase the effectiveness of detecting animals near the source vessel. However, during mealtimes and bathroom breaks, it is sometimes difficult to have two observers on effort, but at least one observer would be on watch during bathroom breaks and mealtimes. Observers would be on duty in shifts of no longer than four hours in duration.

Two observers on the *Langseth* would also be on visual watch during all nighttime ramp-ups of the seismic airguns. A third observer would monitor the passive acoustic monitoring equipment 24 hours a day to detect vocalizing marine mammals present in the action area. In summary, a typical daytime cruise would have scheduled two observers (visual) on duty from the observation tower, and an observer (acoustic) on the passive acoustic monitoring system. Before the start of the seismic survey, Lamont-Doherty would instruct the vessel's crew to assist in detecting marine mammals and implementing mitigation requirements.

The *Langseth* is a suitable platform for marine mammal observations. When stationed on the observation platform, the eye level would be approximately 21.5 m (70.5 ft) above sea level, and the observer would have a good view around the entire vessel. During daytime, the observers would scan the area around the vessel systematically with reticle binoculars (*e.g.,* 7 x 50 Fujinon), Big-eye binoculars (25 x 150), and with the naked eye. During darkness, night vision devices would be available (ITT F500 Series Generation 3 binocular-image intensifier or equivalent), when required. Laser rangefinding binoculars (Leica LRF 1200 laser rangefinder or equivalent) would be available to assist with distance estimation. They are useful in training observers to estimate distances visually, but are generally not useful in measuring distances to animals directly. The user measures distances to animals with the reticles in the binoculars.

Lamont-Doherty would immediately power down or shutdown the airguns when observers see marine mammals within or about to enter the designated exclusion zone. The observer(s) would continue to maintain watch to determine when the animal(s) are outside the exclusion zone by visual confirmation. Airgun operations would not resume until the observer has confirmed that the animal has left the zone, or if not observed after 15 minutes for species with shorter dive durations (small odontocetes and pinnipeds) or 30 minutes for species with longer dive durations (mysticetes and large odontocetes, including sperm, pygmy sperm, dwarf sperm, killer, and beaked whales).

Mitigation Exclusion Zones

Lamont-Doherty would use safety radii to designate exclusion zones and to estimate take for marine mammals. Table 2 shows the distances at which one would expect to receive sound levels (160-, 180-, and 190-dB,) from the airgun array and a single airgun. If the protected species visual observer detects marine mammal(s) within or about to enter the appropriate exclusion zone, the *Langseth* crew would immediately power down the airgun array, or perform a shutdown if necessary (see Shutdown Procedures).

TABLE 2—PREDICTED DISTANCES TO WHICH SOUND LEVELS GREATER THAN OR EQUAL TO 160 re: 1 μPa COULD BE RECEIVED DURING THE PLANNED SURVEY AREAS WITHIN THE SOUTHEAST PACIFIC OCEAN

Source and volume (in^3)	Tow depth (m)	Water depth (m)	Predicted RMS distances[1] (m)		
			190 dB	180 dB	160 dB
Single Bolt airgun (40 in^3)	9 or 12	<100	[2]100	[2]100	1,041
		100 to 1,000	100	100	647
		>1,000	100	100	431
36-Airgun Array (6,600 in^3)	9	<100	591	2,060	22,580
		100 to 1,000	429	1,391	8,670
		>1,000	286	927	5,780
36-Airgun Array (6,600 in^3)	12	<100	710	2,480	27,130
		100 to 1,000	522	1,674	10,362
		>1,000	348	1,116	6,908

[1] Predicted distances based on information presented in Lamont-Doherty's application.

[2] NMFS required Lamont-Doherty to expand the exclusion zone for the mitigation airgun to 100 m (328 ft) in shallow water.

The 180- or 190-dB level shutdown criteria are applicable to cetaceans and pinnipeds, respectively, as specified by NMFS (2000). Lamont-Doherty used these levels to establish the exclusion zones as presented in their application.

Lamont-Doherty used a process to develop and confirm the conservativeness of the mitigation radii for a shallow-water seismic survey in the northeast Pacific Ocean offshore Washington in 2012. Crone *et al.* (2014) analyzed the received sound levels from the 2012 survey and reported that the actual distances to received levels that would constitute the exclusion and buffer zones were two to three times smaller than what Lamont-Doherty's modeling approach had predicted. While these results confirm the role that bathymetry plays in propagation, they also confirm that empirical measurements from the Gulf of Mexico survey likely over-estimated the size of the exclusion zones for the 2012 shallow-water seismic surveys in Washington. NMFS reviewed this information in consideration of how these data reflect on the accuracy of Lamont-Doherty's current modeling approach and we have concluded that the modeling of RMS distances likely results in predicted distances to acoustic thresholds (Table 2) that are conservative, *i.e.,* if actual distances to received sound levels deviate from distances predicted via modeling, actual distances are expected to be lesser, not greater, than predicted distances.

Power-Down Procedures

A power down involves decreasing the number of airguns in use such that the radius of the 180-dB or 190-dB exclusion zone is smaller to the extent that marine mammals are no longer within or about to enter the exclusion zone. A power down of the airgun array can also occur when the vessel is moving from one seismic line to another. During a power down for mitigation, the *Langseth* would operate one airgun (40 in^3). The continued operation of one airgun would alert marine mammals to the presence of the seismic vessel in the area. A shutdown occurs when the *Langseth* suspends all airgun activity.

If the observer detects a marine mammal outside the exclusion zone and the animal is likely to enter the zone, the crew would power down the airguns to reduce the size of the 180-dB or 190-dB exclusion zone before the animal enters that zone. Likewise, if a marine mammal is already within the zone after detection, the crew would power down the airguns immediately. During a power down of the airgun array, the crew would operate a single 40-in^3 airgun which has a smaller exclusion zone. If the observer detects a marine mammal within or near the smaller exclusion zone around the airgun (Table 2), the crew would shut down the single airgun (see next section).

Resuming Airgun Operations After a Power Down

Following a power-down, the *Langseth* crew would not resume full airgun activity until the marine mammal has cleared the 180-dB or 190-dB exclusion zone. The observers would consider the animal to have cleared the exclusion zone if:

- The observer has visually observed the animal leave the exclusion zone; or
- An observer has not sighted the animal within the exclusion zone for 15 minutes for species with shorter dive durations (*i.e.*, small odontocetes or pinnipeds), or 30 minutes for species with longer dive durations (*i.e.*, mysticetes and large odontocetes, including sperm, pygmy sperm, dwarf sperm, and beaked whales); or

The *Langseth* crew would resume operating the airguns at full power after 15 minutes of sighting any species with short dive durations (*i.e.*, small odontocetes or pinnipeds). Likewise, the crew would resume airgun operations at full power after 30 minutes of sighting any species with longer dive durations (*i.e.*, mysticetes and large odontocetes, including sperm, pygmy sperm, dwarf sperm, and beaked whales).

NMFS estimates that the *Langseth* would transit outside the original 180-dB or 190-dB exclusion zone after an eight-minute wait period. This period is based on the average speed of the *Langseth* while operating the airguns (8.5 km/h; 5.3 mph). Because the vessel has transited away from the vicinity of the original sighting during the eight-minute period, implementing ramp-up procedures for the full array after an extended power down (*i.e.*, transiting for an additional 35 minutes from the location of initial sighting) would not meaningfully increase the effectiveness of observing marine mammals approaching or entering the exclusion zone for the full source level and would not further minimize the potential for take. The *Langseth's* observers are continually monitoring the exclusion zone for the full source level while the mitigation airgun is firing. On average, observers can observe to the horizon (10 km; 6.2 mi) from the height of the *Langseth's* observation deck and should be able to say with a reasonable degree of confidence whether a marine mammal would be encountered within this distance before resuming airgun operations at full power.

Shutdown Procedures

The *Langseth* crew would shut down the operating airgun(s) if they see a marine mammal within or approaching the exclusion zone for the single airgun. The crew would implement a shutdown:

(1) If an animal enters the exclusion zone of the single airgun after the crew has initiated a power down; or

(2) If an observer sees the animal is initially within the exclusion zone of the single airgun when more than one airgun (typically the full airgun array) is operating.

Resuming Airgun Operations After a Shutdown

Following a shutdown in excess of eight minutes, the *Langseth* crew would initiate a ramp-up with the smallest airgun in the array (40-in^3). The crew would turn on additional airguns in a sequence such that the source level of the array would increase in steps not exceeding 6 dB per five-minute period over a total duration of approximately 30 minutes. During ramp-up, the observers would monitor the exclusion zone, and if a marine mammal were observed, the *Langseth* crew would implement a power down or shutdown as though the full airgun array were operational.

During periods of active seismic operations, there are occasions when the *Langseth* crew would need to temporarily shut down the airguns due to equipment failure or for maintenance. In this case, if the airguns are inactive longer than eight minutes, the crew would follow ramp-up procedures for a shutdown described earlier and the observers would monitor the full exclusion zone and would implement a power down or shutdown if necessary.

If the full exclusion zone is not visible to the observer for at least 30 minutes prior to the start of operations in either daylight or nighttime, the *Langseth* crew would not commence ramp-up unless at least one airgun (40-in^3 or similar) has been operating during the interruption of seismic survey operations. Given these provisions, it is likely that the vessel's crew would not ramp up the airgun array from a complete shutdown at night or in thick fog, because the outer part of the zone for that array would not be visible during those conditions.

If one airgun has operated during a power down period, ramp-up to full power would be permissible at night or in poor visibility, on the assumption that marine mammals would be alerted to the approaching seismic vessel by the sounds from the single airgun and could move away. The vessel's crew would not initiate a ramp-up of the airguns if an observer sees the marine mammal within or near the applicable exclusion zones during the day or close to the vessel at night.

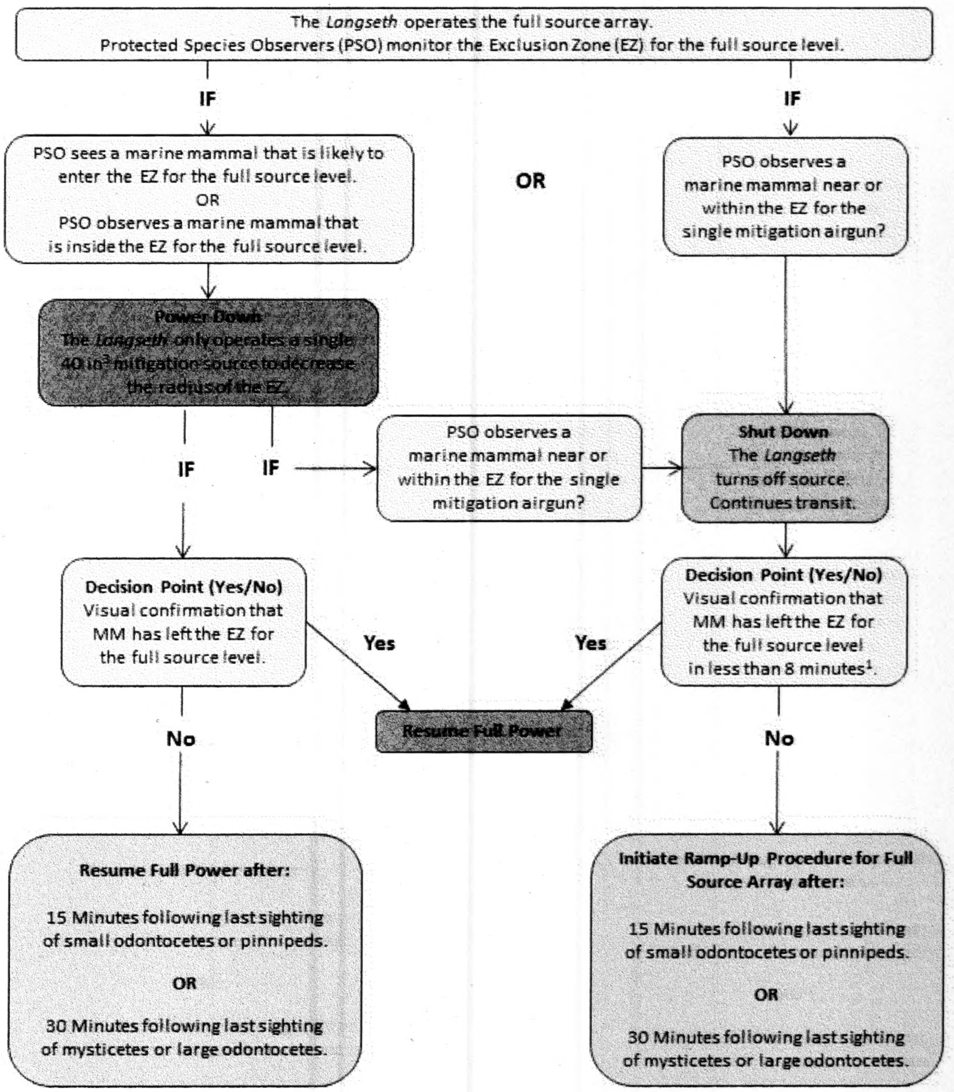
Ramp-Up Procedures

Ramp-up of an airgun array provides a gradual increase in sound levels, and involves a step-wise increase in the number and total volume of airguns firing until the full volume of the airgun array is achieved. The purpose of a ramp-up is to "warn" marine mammals in the vicinity of the airguns, and to provide the time for them to leave the area and thus avoid any potential injury or impairment of their hearing abilities. Lamont-Doherty would follow a ramp-up procedure when the airgun array begins operating after an 8 minute period without airgun operations or when shut down has exceeded that period. Lamont-Doherty has used similar waiting periods (approximately eight to 10 minutes) during previous seismic surveys.

Ramp-up would begin with the smallest airgun in the array (40 in^3). The crew would add airguns in a sequence such that the source level of the array would increase in steps not exceeding six dB per five minute period over a total duration of approximately 30 to 35 minutes. During ramp-up, the observers would monitor the exclusion zone, and if marine mammals are sighted, Lamont-Doherty would implement a power-down or shutdown as though the full airgun array were operational.

If the complete exclusion zone has not been visible for at least 30 minutes prior to the start of operations in either daylight or nighttime, Lamont-Doherty would not commence the ramp-up unless at least one airgun (40 in^3 or similar) has been operating during the interruption of seismic survey operations. Given these provisions, it is likely that the crew would not ramp up the airgun array from a complete shutdown at night or in thick fog, because the outer part of the exclusion zone for that array would not be visible during those conditions. If one airgun has operated during a power-down period, ramp-up to full power would be permissible at night or in poor visibility, on the assumption that marine mammals would be alerted to the approaching seismic vessel by the sounds from the single airgun and could move away. Lamont-Doherty would not initiate a ramp-up of the airguns if an observer sights a marine mammal within or near the applicable exclusion zones. NMFS refers the reader to Figure 1, which presents a flowchart representing the ramp-up, power down, and shutdown protocols described in this notice.

Figure 1. Ramp-up, power down, and shut-down procedures for the *Langseth*.



Current Power-Down and Shut-Down Procedures for the R/V *Langseth*

The Langseth operates the full source array.
Protected Species Observers (PSO) monitor the Exclusion Zone (EZ) for the full source level.
IF
IF
PSO sees a marine mammal that is likely to enter the EZ for the full source level.
OR
PSO observes a marine mammal that is inside the EZ for the full source level.
OR
PSO observes a marine mammal near or within the EZ for the single mitigation airgun?
Power Down
The Langseth only operates a single 40 in³ mitigation source to decrease the radius of the EZ.
IF
IF
PSO observes a marine mammal near or within the EZ for the single mitigation airgun?
Shut Down
The Langseth turns off source. Continues transit.
Decision Point (Yes/No)
Visual confirmation that MM has left the EZ for the full source level.
Yes
Yes
Decision Point (Yes/No)
Visual confirmation that MM has left the EZ for the full source level in less than 8 minutes¹.
Resume Full Power
No
No
Resume Full Power after:
15 Minutes following last sighting of small odontocetes or pinnipeds.
OR
30 Minutes following last sighting of mysticetes or large odontocetes.
Initiate Ramp-Up Procedure for Full Source Array after:
15 Minutes following last sighting of small odontocetes or pinnipeds.
OR
30 Minutes following last sighting of mysticetes or large odontocetes.

[1] **Ramp-Up Procedures**

For a given survey, Lamont-Doherty would calculate a specified period based on the 180-dB exclusion zone radius in relation to the average planned speed of the *Langseth* while surveying . Lamont-Doherty has used similar periods (8-10 minutes) for previous surveys. Ramp up will not occur if a marine mammal or sea turtle has not cleared the exclusion zone for the full array.

Date: November 2015

Special Procedures for Concentrations of Large Whales

The *Langseth* would avoid exposing concentrations of large whales to sounds greater than 160 dB re: 1 µPa within the 160-dB zone and would power down the array, if necessary. For purposes of this survey, a concentration or group of whales would consist of six or more individuals visually sighted that do not appear to be traveling (*e.g.,* feeding, socializing, etc.).

Speed and Course Alterations

If, during seismic data collection, Lamont-Doherty detects a marine mammal outside the exclusion zone that appears likely to enter the exclusion zone based on the animal's position and direction of travel, the *Langseth* would change speed and/or direction if this does not compromise operational safety. Due to the limited maneuverability of the primary survey vessel, altering speed, and/or course can result in an extended period of time to realign the *Langseth* to the transect line. However, if the animal(s) appear likely to enter the exclusion zone, the *Langseth* would undertake further mitigation actions, including a power down or shutdown of the airguns.

Mitigation Conclusions

NMFS has carefully evaluated Lamont-Doherty's mitigation measures in the context of ensuring that we prescribe the means of effecting the least practicable impact on the affected marine mammal species and stocks and their habitat. Our evaluation of potential measures included consideration of the following factors in relation to one another:

- The manner in which, and the degree to which, the successful implementation of the measure is expected to minimize adverse impacts to marine mammals;
- The proven or likely efficacy of the specific measure to minimize adverse impacts as planned; and
- The practicability of the measure for applicant implementation.

Any mitigation measure(s) prescribed by NMFS should be able to accomplish, have a reasonable likelihood of accomplishing (based on current science), or contribute to the accomplishment of one or more of the general goals listed here:

1. Avoidance or minimization of injury or death of marine mammals wherever possible (goals 2, 3, and 4 may contribute to this goal).
2. A reduction in the numbers of marine mammals (total number or number at biologically important time or location) exposed to airgun operations that we expect to result in the take of marine mammals (this goal may contribute to 1, above, or to reducing harassment takes only).
3. A reduction in the number of times (total number or number at biologically important time or location) individuals would be exposed to airgun operations that we expect to result in the take of marine mammals (this goal may contribute to 1, above, or to reducing harassment takes only).
4. A reduction in the intensity of exposures (either total number or number at biologically important time or location) to airgun operations that we expect to result in the take of marine mammals (this goal may contribute to a, above, or to reducing the severity of harassment takes only).
5. Avoidance or minimization of adverse effects to marine mammal habitat, paying special attention to the food base, activities that block or limit passage to or from biologically important areas, permanent destruction of habitat, or temporary destruction/disturbance of habitat during a biologically important time.
6. For monitoring directly related to mitigation—an increase in the probability of detecting marine mammals, thus allowing for more effective implementation of the mitigation.

Based on the evaluation of Lamont-Doherty's planned measures, as well as other measures developed by NMFS (*i.e.,* special procedures for concentrations of large whales), NMFS has determined that the planned mitigation measures provide the means of effecting the least practicable impact on marine mammal species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Monitoring Measures

In order to issue an Incidental Harassment Authorization for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth "requirements pertaining to the monitoring and reporting of such taking." The MMPA implementing regulations at 50 CFR 216.104 (a)(13) indicate that requests for Authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that we expect to be present in the action area.

Monitoring measures prescribed by NMFS should accomplish one or more of the following general goals:

1. An increase in the probability of detecting marine mammals, both within the mitigation zone (thus allowing for more effective implementation of the mitigation) and during other times and locations, in order to generate more data to contribute to the analyses mentioned later;
2. An increase in our understanding of how many marine mammals would be affected by seismic airguns and other active acoustic sources and the likelihood of associating those exposures with specific adverse effects, such as behavioral harassment, temporary or permanent threshold shift;
3. An increase in our understanding of how marine mammals respond to stimuli that we expect to result in take and how those anticipated adverse effects on individuals (in different ways and to varying degrees) may impact the population, species, or stock (specifically through effects on annual rates of recruitment or survival) through any of the following methods:
   a. Behavioral observations in the presence of stimuli compared to observations in the absence of stimuli (*i.e.,* to be able to accurately predict received level, distance from source, and other pertinent information);
   b. Physiological measurements in the presence of stimuli compared to observations in the absence of stimuli (*i.e.,* to be able to accurately predict received level, distance from source, and other pertinent information);
   c. Distribution and/or abundance comparisons in times or areas with concentrated stimuli versus times or areas without stimuli;
4. An increased knowledge of the affected species; and
5. An increase in our understanding of the effectiveness of certain mitigation and monitoring measures.

Lamont-Doherty plans to conduct marine mammal monitoring during the planned project to supplement the mitigation measures that include real-time monitoring (see "Vessel-based Visual Mitigation Monitoring" above), and to satisfy the monitoring requirements of the Authorization.

Vessel-Based Passive Acoustic Monitoring

Passive acoustic monitoring would complement the visual mitigation monitoring program, when practicable. Visual monitoring typically is not effective during periods of poor visibility or at night, and even with good visibility, is unable to detect marine mammals when they are below the surface or beyond visual range. Passive acoustic monitoring can improve detection, identification, and localization of cetaceans when used in conjunction with visual observations. The passive acoustic monitoring would serve to alert visual observers (if on duty) when vocalizing cetaceans are detected. It is only useful when marine mammals call, but it can be effective either by day or by night, and does not depend on good visibility. The acoustic observer would monitor the system in real time so that he/she can advise the visual observers if they acoustically detect cetaceans.

The passive acoustic monitoring system consists of hardware (*i.e.*, hydrophones) and software. The "wet end" of the system consists of a towed hydrophone array connected to the vessel by a tow cable. The tow cable is 250 m (820.2 ft) long and the hydrophones are fitted in the last 10 m (32.8 ft) of cable. A depth gauge, attached to the free end of the cable, typically towed at depths less than 20 m (65.6 ft). The *Langseth* crew would deploy the array from a winch located on the back deck. A deck cable would connect the tow cable to the electronics unit in the main computer lab where the acoustic station, signal conditioning, and processing system would be located. The Pamguard software amplifies, digitizes, and then processes the acoustic signals received by the hydrophones. The system can detect marine mammal vocalizations at frequencies up to 250 kHz.

One acoustic observer, an expert bioacoustician with primary responsibility for the passive acoustic monitoring system would be aboard the *Langseth* in addition to the other visual observers who would rotate monitoring duties. The acoustic observer would monitor the towed hydrophones 24 hours per day during airgun operations and during most periods when the *Langseth* is underway while the airguns are not operating. However, passive acoustic monitoring may not be possible if damage occurs to both the primary and back-up hydrophone arrays during operations. The primary passive acoustic monitoring streamer on the *Langseth* is a digital hydrophone streamer. Should the digital streamer fail, back-up systems should include an analog spare streamer and a hull-mounted hydrophone.

One acoustic observer would monitor the acoustic detection system by listening to the signals from two channels via headphones and/or speakers and watching the real-time spectrographic display for frequency ranges produced by cetaceans. The observer monitoring the acoustical data would be on shift for one to six hours at a time. The other observers would rotate as an acoustic observer, although the expert acoustician would be on passive acoustic monitoring duty more frequently.

When the acoustic observer detects a vocalization while visual observations are in progress, the acoustic observer on duty would contact the visual observer immediately, to alert him/her to the presence of cetaceans (if they have not already been seen), so that the vessel's crew can initiate a power down or shutdown, if required. The observer would enter the information regarding the call into a database. Data entry would include an acoustic encounter identification number, whether it was linked with a visual sighting, date, time when first and last heard and whenever any additional information was recorded, position and water depth when first detected, bearing if determinable, species or species group (*e.g.*, unidentified dolphin, sperm whale), types and nature of sounds heard (*e.g.*, clicks, continuous, sporadic, whistles, creaks, burst pulses, strength of signal, etc.), and any other notable information. Acousticians record the acoustic detection for further analysis.

Observer Data and Documentation

Observers would record data to estimate the numbers of marine mammals exposed to various received sound levels and to document apparent disturbance reactions or lack thereof. They would use the data to help better understand the impacts of the activity on marine mammals and to estimate numbers of animals potentially 'taken' by harassment (as defined in the MMPA). They will also provide information needed to order a power down or shut down of the airguns when a marine mammal is within or near the exclusion zone.

When an observer makes a sighting, they will record the following information:

1. Species, group size, age/size/sex categories (if determinable), behavior when first sighted and after initial sighting, heading (if consistent), bearing and distance from seismic vessel, sighting cue, apparent reaction to the airguns or vessel (*e.g.*, none, avoidance, approach, paralleling, etc.), and behavioral pace.
2. Time, location, heading, speed, activity of the vessel, sea state, visibility, and sun glare.
3. The observer will record the data listed under (2) at the start and end of each observation watch, and during a watch whenever there is a change in one or more of the variables.
4. Observers will record all observations and power downs or shutdowns in a standardized format and will enter data into an electronic database. The observers will verify the accuracy of the data entry by computerized data validity checks during data entry and by subsequent manual checking of the database. These procedures will allow the preparation of initial summaries of data during and shortly after the field program, and will facilitate transfer of the data to statistical, graphical, and other programs for further processing and archiving.

Results from the vessel-based observations will provide:

1. The basis for real-time mitigation (airgun power down or shutdown).
2. Information needed to estimate the number of marine mammals potentially taken by harassment, which Lamont-Doherty must report to the Office of Protected Resources.
3. Data on the occurrence, distribution, and activities of marine mammals and turtles in the area where Lamont-Doherty would conduct the seismic study.
4. Information to compare the distance and distribution of marine mammals and turtles relative to the source vessel at times with and without seismic activity.
5. Data on the behavior and movement patterns of marine mammals detected during non-active and active seismic operations.

Reporting Measures

Lamont-Doherty will submit a report to NMFS and to NSF within 90 days after the end of the cruise. The report will describe the operations conducted and sightings of marine mammals near the operations. The report will provide full documentation of methods, results, and interpretation pertaining to all monitoring. The 90-day report will summarize the dates and locations of seismic operations, and all marine mammal sightings (dates, times, locations, activities, associated seismic survey activities).

The report will also include estimates of the number and nature of exposures that occurred above the harassment threshold based on the observations and in consideration of the detectability of the marine mammal species observed (*e.g.*, in consideration of factors such as g(0) or f(0)). Lamont-Doherty must provide an estimate of the number (by species) of marine mammals that may have been exposed (based on modeling results and accounting for animals at the surface but not detected [*i.e.*, g(0) values] and for animals present but underwater and not available for sighting [*i.e.*, f(0) values]) to the seismic activity at received levels greater than or equal to 160 dB re: 1 µPa and/or 180 dB re 1 µPa for cetaceans and 190-dB re 1 µPa for pinnipeds. NMFS includes this requirement for post-survey exposure estimates in acknowledgement of the uncertainty inherent in the pre-survey take estimates, and these post-survey corrections are intended to provide a relative qualitative sense of the accuracy of the pre-survey take estimates based on the marine mammals actually observed during the survey and the factors described above. However, it is important to note that these corrections, while helpful in utilizing the most appropriate surrogate numbers, will utilize values determined by species behavior in other areas (f(0)) and detection probabilities calculated for different observers in different environmental conditions (g(0)). Additionally, correction factors of this nature are likely more effective over more extensive targeted marine mammal survey efforts, whereas for a shorter survey such as the one considered here, the patchiness of marine mammal occurrence makes quantitative accuracy less likely. Therefore, while the corrected post-survey exposure estimates certainly improve upon exposure assumptions based solely on observation, and may appropriately be used to qualitatively inform future take estimates, they should not be construed as an indicator that the corrected number of marine mammals equates to the number of marine mammals definitively taken during the survey.

In the unanticipated event that the specified activity clearly causes the take of a marine mammal in a manner not permitted by the authorization (if issued), such as an injury, serious injury, or mortality (*e.g.*, ship-strike, gear interaction, and/or entanglement), Lamont-Doherty shall immediately cease the specified activities and immediately report the take to the Chief Permits and Conservation Division, Office of Protected Resources, NMFS. The report must include the following information:

- Time, date, and location (latitude/longitude) of the incident;
- Name and type of vessel involved;
- Vessel's speed during and leading up to the incident;
- Description of the incident;
- Status of all sound source use in the 24 hours preceding the incident;
- Water depth;
- Environmental conditions (*e.g.*, wind speed and direction, Beaufort sea state, cloud cover, and visibility);
- Description of all marine mammal observations in the 24 hours preceding the incident;
- Species identification or description of the animal(s) involved;
- Fate of the animal(s); and
- Photographs or video footage of the animal(s) (if equipment is available).

Lamont-Doherty shall not resume its activities until NMFS is able to review the circumstances of the prohibited take. NMFS would work with Lamont-Doherty to determine what is necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. Lamont-Doherty may not resume their activities until notified by NMFS via letter, email, or telephone.

In the event that Lamont-Doherty discovers an injured or dead marine mammal, and the lead visual observer determines that the cause of the injury or death is unknown and the death is relatively recent (*i.e.*, in less than a moderate state of decomposition as we describe in the next paragraph), Lamont-Doherty will immediately report the incident to the Chief Permits and Conservation Division, Office of Protected Resources, NMFS. The report must include the same information identified in the paragraph above this section. Activities may continue while NMFS reviews the circumstances of the incident. NMFS would work with Lamont-Doherty to determine whether modifications in the activities are appropriate.

In the event that Lamont-Doherty discovers an injured or dead marine mammal, and the lead visual observer determines that the injury or death is not associated with or related to the authorized activities (*e.g.*, previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), Lamont-Doherty would report the incident to the Chief Permits and Conservation Division, Office of Protected Resources, NMFS, within 24 hours of the discovery. Lamont-Doherty would provide photographs or video footage (if available) or other documentation of the stranded animal sighting to NMFS.

Estimated Take by Incidental Harassment

Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines "harassment" as: any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment].

Acoustic stimuli (*i.e.*, increased underwater sound) generated during the operation of the airgun array may have the potential to result in the behavioral disturbance of some marine mammals and may have an even smaller potential to result in permanent threshold shift (non-lethal injury) of some marine mammals. NMFS expects that the mitigation and monitoring measures would minimize the possibility of injurious or lethal takes. However, NMFS cannot discount the possibility (albeit small) that exposure to sound from the planned survey could result in non-lethal injury (Level A harassment). Thus, NMFS authorizes take by Level B harassment and Level A harassment resulting from the operation of the sound sources for the planned seismic survey based upon the current acoustic exposure criteria shown in Table 3, subject to the limitations in take described in Tables 4–7 later in this notice.

TABLE 3—NMFS'S CURRENT ACOUSTIC EXPOSURE CRITERIA

Criterion	Criterion definition	Threshold
Level A Harassment (Injury)	Permanent Threshold Shift (PTS) (Any level above that which is known to cause TTS).	180 dB re 1 microPa-m (cetaceans)/190 dB re 1 microPa-m (pinnipeds) root mean square (rms).
Level B Harassment	Behavioral Disruption (for impulse noises)	160 dB re 1 microPa-m (rms).

NMFS's practice is to apply the 160 dB re: 1 μPa received level threshold for underwater impulse sound levels to predict whether behavioral disturbance that rises to the level of Level B harassment is likely to occur. NMFS's practice is to apply the 180 dB or 190 dB re: 1 μPa (for cetaceans and pinnipeds, respectively) received level threshold for underwater impulse sound levels to predict whether permanent threshold shift (auditory injury), which we consider as harassment (Level A), is likely to occur.

Acknowledging Uncertainties in Estimating Take

Given the many uncertainties in predicting the quantity and types of impacts of sound on marine mammals, it is common practice for us to estimate how many animals are likely to be present within a particular distance of a given activity, or exposed to a particular level of sound. We use this information to predict how many animals potentially could be taken. In practice, depending on the amount of information available to characterize daily and seasonal movement and distribution of affected marine mammals, distinguishing between the numbers of individuals harassed and the instances of harassment can be difficult to parse. Moreover, when one considers the duration of the activity, in the absence of information to predict the degree to which individual animals are likely exposed repeatedly on subsequent days, one assumption is that entirely new animals could be exposed every day, which results in a take estimate that in some circumstances overestimates the number of individuals harassed.

The following sections describe Lamont-Doherty's and NMFS's methods to estimate take by incidental harassment. We base these estimates on the number of marine mammals that are estimated to be exposed to seismic airgun sound levels above the Level B harassment threshold of 160 dB during a total of approximately 9,633 km (5,986 mi) of transect lines in the southeast Pacific Ocean.

Density Estimates: Lamont-Doherty was unable to identify any systematic aircraft- or ship-based surveys conducted for marine mammals in waters of the southeast Pacific Ocean offshore Chile. Lamont-Doherty used densities from NMFS Southwest Fisheries Science Center (SWFSC) cruises (Ferguson and Barlow, 2001, 2003; Barlow 2003, 2010; Forney, 2007) in the California Current, which is similar to the Humboldt Current Coastal area in which the planned surveys are located. Both are eastern boundary currents that feature narrow continental shelves, upwelling, high productivity, and fluctuating fishery resources (sardines and anchovies). The densities used were survey effort-weighted means for the locations (blocks or states). In cases where multiple density estimates existed for an area, Lamont-Doherty used the highest density range (summer/fall) for each species within the survey area. We refer the reader to Lamont-Doherty's application for detailed information on how Lamont-Doherty calculated densities for marine mammals from the SWFSC cruises.

For blue whales in the southern survey area, NMFS used the density (9.56/km^2) reported by Galletti Vernazzani *et al.* (2012) for approximately four days of the planned southern survey to account for potential survey operations occurring near a known foraging area between 39° S and 44° S. For the remaining 31 days of the planned survey, NMFS used the density estimate presented in Lamont-Doherty's application (2.07/km^2). NMFS considers Lamont-Doherty's approach to calculating densities for the remaining marine mammal species in the survey areas as the best available information. We present the estimated densities (when available) in Tables 4, 5, and 6 in this notice.

Modeled Number of Instances of Exposures: Lamont-Doherty will conduct the planned seismic surveys offshore Chile in the southeast Pacific Ocean and presented NMFS with estimates of the anticipated numbers of instances that marine mammals could be exposed to sound levels greater than or equal to 160, 180, and 190 dB re: 1 μPa during the planned seismic survey (outside the Chilean territorial sea) in Tables 3, 4, and 5 in their application. NMFS independently reviewed these estimates and presents revised estimates of the anticipated numbers of instances that marine mammals could be exposed to sound levels greater than or equal to 160, 180, and 190 dB re: 1 μPa during the planned seismic survey (outside the Chilean territorial sea) in Tables 4, 5, and 6 in this notice. Table 7 presents the total numbers of instances of take that NMFS authorizes. As described above, NMFS cannot authorize the incidental take of marine mammals in the territorial seas of foreign nations, as the MMPA does not apply in those waters; therefore the total numbers of instances of take that NMFS authorizes represents only the takes predicted to occur outside of the Chilean territorial sea (Table 7).

Take Estimate Method for Species with Density Information: Briefly, we take the estimated density of marine mammals within an area (animals/km^2) and multiply that number by the daily ensonified area (km^2). The product (rounded) is the number of instance of take within one day. We then multiply the number of instances of take within one day by the number of survey days (plus 25 percent contingency). The result is an estimate of the potential number of instances that marine mammals could be exposed to airgun sounds above the Level B harassment threshold (*i.e.,* the 160 dB ensonified area minus the 180/190-dB ensonified area) and the Level A harassment threshold (*i.e.,* the 180/190-dB ensonified area only) over the duration of each planned survey.

There is some uncertainty about the representativeness of the estimated density data and the assumptions used in their calculations. Oceanographic conditions, including occasional El Niño and La Niña events, influence the distribution and numbers of marine mammals present in the eastern tropical Pacific Ocean, resulting in considerable year-to-year variation in the distribution and abundance of many marine mammal species. Thus, for some species, the densities derived from past surveys may not be representative of the densities that would be encountered during the planned seismic surveys. However, the approach used is based on the best available data.

In many cases, this estimate of instances of exposures is likely an overestimate of the number of individuals that are taken, because it assumes 100 percent turnover in the area every day, (*i.e.,* that each new day results in takes of entirely new individuals with no repeat takes of the same individuals over the three periods (northern: 35 days; central: 6 days; and southern: 34 days) including contingency. It is difficult to quantify to what degree this method overestimates the number of individuals potentially taken. Except as described later for a few specific species, NMFS uses this number of instances as the estimate of individuals (and authorized take).

Take Estimates for Species with Less than One Instance of Exposure: Using the approach described earlier, the model generated instances of take for some species that were less than one over the 75 total survey days. Those species include: Bryde's, dwarf sperm, killer, and sei whale. NMFS used data based on dedicated survey sighting information from the Atlantic Marine Assessment Program for Protected Species (AMAPPS) surveys in 2010, 2011, and 2013 (AMAPPS, 2010, 2011, 2013) to estimate take and assumed that Lamont-Doherty could potentially encounter one group of each species during the planned seismic survey. NMFS believes it is reasonable to use the average (mean) group size (weighted by effort and rounded up) from the AMMAPS surveys for Bryde's whale (2), dwarf sperm whale (2), killer whale (4), and sei whale (3) to derive a reasonable estimate of take for eruptive occurrences of each these species only once for each survey.

Take Estimates for Species with No Density Information: Density information for the southern right whale, pygmy right whale, Antarctic minke whale, sei whale, dwarf sperm whale, Shephard's beaked whale, pygmy beaked whale, southern bottlenose whale, hourglass dolphin, pygmy killer whale, false killer whale; short-finned pilot whale, Juan Fernandez fur seal, and southern elephant seal in the southeast Pacific Ocean is data poor or non-existent. When density estimates were not available for a particular survey leg, NMFS used data based on dedicated survey sighting information from the Atlantic Marine Assessment Program for Protected Species (AMAPPS) surveys in 2010, 2011, and 2013 (AMAPPS, 2010, 2011, 2013) and from Santora (2012) to estimate mean group size and take for these species. NMFS assumed that Lamont-Doherty could potentially encounter one group of each species each day during the seismic survey. NMFS believes it is reasonable to use the average (mean) group size (weighted by effort and rounded up) for each species multiplied by the number of survey days to derive an estimate of take from potential encounters.

TABLE 4—DENSITIES OF MARINE MAMMALS AND ESTIMATES OF INCIDENTS OF EXPOSURE TO ≥160 AND 180 OR 190 dB re 1 μPa rms PREDICTED DURING THE NORTHERN SEISMIC SURVEY IN THE SOUTHEAST PACIFIC OCEAN IN 2016/2017 (OUTSIDE CHILEAN TERRITORIAL SEA)

Species	Density estimate [1]	Modeled number of instances of exposures to sound levels ≥160, 180, and 190 dB [2]	Level A take [3]	Level B take
Southern right whale	0	105, 0, -	0	105
Humpback whale	0.32	35, 0, -	0	35
Common (dwarf) minke whale	0.34	35, 0, -	0	35
Antarctic minke whale	0	70, 0, -	0	70
Bryde's whale	0.47	35, 0, 0	0	35
Sei whale	0	105, 0, -	0	105
Fin whale	1.4	105, 35, -	35	105
Blue whale	0.54	35, 0, -	0	35
Sperm whale	1.19	70, 0, -	0	70
Dwarf sperm whale	8.92	630, 105, -	105	630
Pygmy sperm whale	2.73	210, 35, -	35	210
Cuvier's beaked whale	2.36	175, 35, -	35	175
Pygmy beaked whale	0.7	35, 0, -	0	35
Gray's beaked whale	1.95	140, 35, -	35	140
Blainville's beaked whale	1.95	140, 35, -	35	140
Rough-toothed dolphin	7.05	490, 105, -	105	490
Common bottlenose dolphin	18.4	1,330, 245, -	245	1,330
Striped dolphin	61.4	4,410, 805, -	805	4,410
Short-beaked common dolphin	356.3	25,515, 4,725, -	4,725	25,515
Long-beaked common dolphin	50.3	3,605, 665, -	665	3,605
Dusky dolphin	13.7	980, 175, -	175	980
Southern right whale dolphin	3.34	245, 35, -	35	245
Risso's dolphin	29.8	2,135, 385, -	385	2,135
Pygmy killer whale	1.31	105, 0, -	0	105
False killer whale	0.63	35, 0, -	0	35
Killer whale	0.23	4, 0, -	0	4
Short-finned pilot whale	0	700, 0, -	0	700
Long-finned pilot whale	1.09	70, 0, -	0	70
Burmeister's porpoise	5.15	385, 70, -	70	385
Juan Fernandez fur seal	0	70, -, 0	0	70
South American fur seal	37.9	2,730, -, 490	490	2,730
South American sea lion	393	28,140, -, 5,215	5,215	28,140

[1] Densities shown (when available) are 1,000 animals per km^2. See Lamont-Doherty's application and text in this notice for a summary of how Lamont-Doherty derived density estimates for certain species. For species without density estimates, see text in this notice for an explanation of NMFS's methodology to derive take estimates.

[2] Take modeled using a daily method for calculating ensonified area: Estimated density multiplied by the daily ensonified area to derive instances of take in one day (rounded) multiplied by the number of survey days with 25 percent contingency (35) Level B take = modeled instances of exposure within the 160-dB ensonified area minus the 180-dB or 190-dB ensonified area. Level A take = modeled instances of exposures within the 180-dB or 190-dB ensonified area only. Modeled instances of exposures include adjustments for species with no density information or with species having less than one instance of exposure (see text for sources).

[3] The Level A estimates are overestimates of predicted impacts to marine mammals as the estimates do not take into consideration the required mitigation measures for shutdowns or power downs if a marine mammal is likely to enter the 180 or 190 dB exclusion zone while the airguns are active.

TABLE 5—DENSITIES OF MARINE MAMMALS AND ESTIMATES OF INCIDENTS OF EXPOSURE TO ≥160 AND 180 OR 190 dB re 1 μPa rms PREDICTED DURING THE CENTRAL SEISMIC SURVEY IN THE SOUTHEAST PACIFIC OCEAN IN 2016/2017 (OUTSIDE CHILEAN TERRITORIAL SEA)

Species	Density estimate [1]	Modeled number of instances of exposures to sound levels ≥160, 180, and 190 dB [2]	Level A take [3]	Level B take
Southern right whale	0	18, 0, -	0	18
Pygmy right whale	0	18, 0, -	0	18

TABLE 5—DENSITIES OF MARINE MAMMALS AND ESTIMATES OF INCIDENTS OF EXPOSURE TO ≥160 AND 180 OR 190 dB re 1 μPa rms PREDICTED DURING THE CENTRAL SEISMIC SURVEY IN THE SOUTHEAST PACIFIC OCEAN IN 2016/2017 (OUTSIDE CHILEAN TERRITORIAL SEA)—Continued

Species	Density estimate [1]	Modeled number of instances of exposures to sound levels ≥160, 180, and 190 dB [2]	Level A take [3]	Level B take
Humpback whale	0.43	6, 0, -	0	6
Common (dwarf) minke whale	0.34	6, 0, -	0	6
Antarctic minke whale	0	12, 0, -	0	12
Bryde's whale	0.41	6, 0, -	0	6
Sei whale	0	18, 0, -	0	18
Fin whale	1.96	18, 6, -	6	18
Blue whale	2.1	18, 6, -	6	18
Sperm whale	1.22	12, 0, -	0	12
Dwarf sperm whale	7.98	78, 12, -	12	78
Pygmy sperm whale	2.98	30, 6, -	6	30
Cuvier's beaked whale	3.02	30, 6, -	6	30
Shepard's beaked whale	0	18, 0, -	0	18
Hector's beaked whale	1.54	18, 0, -	0	18
Pygmy beaked whale	0.55	6, 0, -	0	6
Gray's beaked whale	1.54	18, 0, -	0	18
Blainville's beaked whale	1.54	18, 0, -	0	18
Andrew's beaked whale	1.54	18, 0, -	0	18
Strap-toothed beaked whale	1.54	18, 0, -	0	18
Spade-toothed beaked whale	1.54	18, 0, -	0	18
Chilean dolphin	21.2	210, 36, -	36	210
Common bottlenose dolphin	12.3	120, 24, -	24	120
Striped dolphin	46.7	462, 84, -	84	462
Short-beaked common dolphin	503.5	4,998, 908, -	906	4,998
Dusky dolphin	14.8	144, 24, -	24	144
Peale's dolphin	21.2	210, 36, -	36	210
Hourglass dolphin	0	30, 0, -	0	30
Southern right whale dolphin	6.07	60, 12, -	12	60
Risso's dolphin	21.2	210, 36, -	36	210
Pygmy killer whale	0	12, 0, -	0	12
False killer whale	0.54	6, 0, -	0	6
Killer whale	0.28	4, 0, -	0	4
Short-finned pilot whale	0	120, 0, -	0	120
Long-finned pilot whale	0.94	12, 0, -	0	12
Burmeister's porpoise	4.92	48, 6, -	6	48
Juan Fernandez fur seal	0	12, -, 0	0	12
South American fur seal	37.9	378, -, 66	66	378
South American sea lion	393	3,900, -, 708	708	3,900
Southern elephant seal	0	24, -, 0	0	24

[1] Densities shown (when available) are 1,000 animals per km². See Lamont-Doherty's application and text in this notice for a summary of how Lamont-Doherty derived density estimates for certain species. For species without density estimates, see text in this notice for an explanation of NMFS's methodology to derive take estimates.

[2] Take modeled using a daily method for calculating ensonified area: Estimated density multiplied by the daily ensonified area to derive instances of take in one day (rounded) multiplied by the number of survey days with 25 percent contingency (35) Level B take = modeled instances of exposure within the 160-dB ensonified area minus the 180-dB or 190-dB ensonified area. Level A take = modeled instances of exposures within the 180-dB or 190-dB ensonified area only. Modeled instances of exposures include adjustments for species with no density information or with species having less than one instance of exposure (see text for sources).

[3] The Level A estimates are overestimates of predicted impacts to marine mammals as the estimates do not take into consideration the required mitigation measures for shutdowns or power downs if a marine mammal is likely to enter the 180 or 190 dB exclusion zone while the airguns are active.

TABLE 6—DENSITIES OF MARINE MAMMALS AND ESTIMATES OF INCIDENTS OF EXPOSURE TO ≥160 AND 180 OR 190 dB re 1 μPa rms PREDICTED DURING THE SOUTHERN SEISMIC SURVEY IN THE SOUTHEAST PACIFIC OCEAN IN 2016/2017 (OUTSIDE CHILEAN TERRITORIAL SEA)

Species	Density estimate [1]	Modeled number of instances of exposures to sound levels ≥160, 180, and 190 dB [2]	Level A take [3]	Level B take
Southern right whale	0	102, 0, -	0	102
Pygmy right whale	0	102, 0, -	0	102
Humpback whale	1.22	102, 0, -	0	102
Common (dwarf) minke whale	0.61	34, 0, -	0	34

TABLE 6—DENSITIES OF MARINE MAMMALS AND ESTIMATES OF INCIDENTS OF EXPOSURE TO ≥160 AND 180 OR 190 dB re 1 μPa rms PREDICTED DURING THE SOUTHERN SEISMIC SURVEY IN THE SOUTHEAST PACIFIC OCEAN IN 2016/2017 (OUTSIDE CHILEAN TERRITORIAL SEA)—Continued

Species	Density estimate [1]	Modeled number of instances of exposures to sound levels ≥160, 180, and 190 dB [2]	Level A take [3]	Level B take
Antarctic minke whale	0	68, 0, -	0	68
Bryde's whale	0.03	2, 0, -	0	2
Sei whale	0.02	3, 0, -	0	3
Fin whale	2.43	170, 34, -	34	170
Blue whale (Feb-Apr)	9.56	80, 12, -	12	80
Blue whale (May–Jan)	2.07	124, 31, -	31	124
Sperm whale	1.32	102, 0, -	0	102
Dwarf sperm whale	0	68, 0, -	0	68
Pygmy sperm whale	4.14	306, 34, -	34	306
Cuvier's beaked whale	4.02	272, 34, -	34	272
Shepard's beaked whale	0	102, 0, -	0	102
Hector's beaked whale	0.31	34, 0, -	0	34
Pygmy beaked whale	0	102, 0, -	0	102
Gray's beaked whale	1.95	136, 34, -	34	136
Blainville's beaked whale	0.31	34, 0, -	0	34
Andrew's beaked whale	0.31	34, 0, -	0	34
Strap-toothed beaked whale	0.31	34, 0, -	0	34
Spade-toothed beaked whale	0.31	34, 0, -	0	34
Southern bottlenose whale	0	102, 0, -	0	102
Chilean dolphin	10.9	748, 136, 0	136	748
Common bottlenose dolphin	2.72	204, 34, -	34	204
Striped dolphin	17.7	1,224, 204, -	204	1,224
Short-beaked common dolphin	516.9	36,210, 5,950, -	5,950	36,210
Dusky dolphin	29.9	2,108, 340, -	340	2,108
Peale's dolphin	10.9	748, 136, -	136	748
Hourglass dolphin	0	170, 0, -	0	170
Southern right whale dolphin	9.79	680, 102, -	102	680
Risso's dolphin	10.9	748, 136, -	136	748
Pygmy killer whale	0	68, 0, -	0	68
False killer whale	0	238, 0, -	0	238
Killer whale	0.73	68, 0, -	0	68
Short-finned pilot whale	0	680, 0, -	0	680
Long-finned pilot whale	0.53	34, 0, -	0	34
Burmeister's porpoise	55.4	3,876, 646, -	646	3,876
Juan Fernandez fur seal	0	68, -, 0	0	68
South American fur seal	37.9	2,652, -, 442	442	2,652
South American sea lion	393	27,540, -, 4,522	4,522	27,540
Southern elephant seal	0	136, -, 0	0	136

[1] Densities shown (when available) are 1,000 animals per km². See Lamont-Doherty's application and text in this notice for a summary of how Lamont-Doherty derived density estimates for certain species. For species without density estimates, see text in this notice for an explanation of NMFS's methodology to derive take estimates.

[2] Take modeled using a daily method for calculating ensonified area: Estimated density multiplied by the daily ensonified area to derive instances of take in one day (rounded) multiplied by the number of survey days with 25 percent contingency (35) Level B take = modeled instances of exposure within the 160–dB ensonified area minus the 180–dB or 190–dB ensonified area. Level A take = modeled instances of exposures within the 180–dB or 190–dB ensonified area only. Modeled instances of exposures include adjustments for species with no density information or with species having less than one instance of exposure (see text for sources).

[3] The Level A estimates are overestimates of predicted impacts to marine mammals as the estimates do not take into consideration the required mitigation measures for shutdowns or power downs if a marine mammal is likely to enter the 180 or 190 dB exclusion zone while the airguns are active.

TABLE 7—TAKE AUTHORIZED DURING THE NORTHERN, CENTRAL, AND SOUTHERN SEISMIC SURVEY OFF CHILE IN THE SOUTHEAST PACIFIC OCEAN IN 2016/2017 BASED ON TOTAL PREDICTED INCIDENTS OF EXPOSURE TO ≥160 AND 180 OR 190 dB re 1 μPa rms (OUTSIDE CHILEAN TERRITORIAL SEA)

Species	Level A take [1]	Level B take	Total take	Percent of population [2]
Southern right whale	0	225	225	1.9%
Pygmy right whale	0	120	120	Unknown
Humpback whale	0	143	143	0.3
Common (dwarf) minke whale	0	75	75	0.02
Antarctic minke whale	0	150	150	0.03
Bryde's whale	0	43	43	0.1
Sei whale	0	126	126	1.3
Fin whale	75	293	368	1.7

TABLE 7—TAKE AUTHORIZED DURING THE NORTHERN, CENTRAL, AND SOUTHERN SEISMIC SURVEY OFF CHILE IN THE SOUTHEAST PACIFIC OCEAN IN 2016/2017 BASED ON TOTAL PREDICTED INCIDENTS OF EXPOSURE TO ≥160 AND 180 OR 190 dB re 1 μPa rms (OUTSIDE CHILEAN TERRITORIAL SEA)—Continued

Species	Level A take[1]	Level B take	Total take	Percent of population[2]
Blue whale	49	257	306	3.1
Sperm whale	0	184	184	0.1
Dwarf sperm whale	117	776	893	0.5
Pygmy sperm whale	75	546	621	0.4
Cuvier's beaked whale	75	477	552	2.8
Shepard's beaked whale	0	120	120	0.5
Pygmy beaked whale	0	143	143	0.6
Gray's beaked whale	69	294	363	1.4
Blainville's beaked whale	35	192	227	0.9
Hector's beaked whale	0	52	52	0.2
Gray's beaked whale	69	294	363	1.4
Andrew's beaked whale	0	52	52	0.2
Strap-toothed beaked whale	0	52	52	0.2
Spade-toothed beaked whale	0	52	52	0.2
Southern bottlenose whale	0	102	102	0.1
Chilean dolphin	172	958	1,130	11.3
Rough-toothed dolphin	105	490	595	0.1
Common bottlenose dolphin	303	1,654	1,957	0.1
Striped dolphin	1,093	6,096	7,189	0.1
Short-beaked common dolphin	11,581	66,723	78,304	4.4
Long-beaked common dolphin	665	3,605	4,270	2.9
Dusky dolphin	539	3,232	3,771	14.6
Peale's dolphin	172	958	1,130	Unknown
Hourglass dolphin	0	200	200	0.1
Southern right whale dolphin	149	985	1,134	Unknown
Risso's dolphin	557	3,093	3,650	3.3
Pygmy killer whale	0	185	185	0.5
False killer whale	0	279	279	0.7
Killer whale	0	76	76	0.2
Short-finned pilot whale	0	1,500	1,500	0.3
Long-finned pilot whale	0	116	116	0.1
Burmeister's porpoise	722	4,309	5,031	Unknown
Juan Fernandez fur seal	0	150	150	0.5
South American fur seal	998	5,760	6,758	2.7
South American sea lion	10,445	59,580	70,025	17.6
Southern elephant seal	0	160	160	0.04

[1] The Level A estimates are overestimates of predicted impacts to marine mammals as the estimates do not take into consideration the required mitigation measures for shutdowns or power downs if a marine mammal is likely to enter the 180 or 190 dB exclusion zone while the airguns are active.

[2] Authorized Level A and B takes (used by NMFS as proxy for number of individuals exposed) expressed as the percent of the population listed in Table 1 in this notice. Unknown = Abundance size not available.

Lamont-Doherty did not estimate any additional take from sound sources other than airguns. NMFS does not expect the sound levels produced by the echosounder and sub-bottom profiler to exceed the sound levels produced by the airguns. During the estimated 10 nm of transit that is expected to occur between the three planned survey locations, the use of the MBES and SBP may occur independent of seismic airgun operation. This use of the MBES and SBP in the absence of airgun use was not explicitly described in the **Federal Register** notice for the proposed IHA (81 FR 23117; April 19, 2016). While sound from MBES and SBP has the potential to result in harassment of marine mammals, any potential for takes that could occur as a result of the MBES and SBP within those 10 nm of transit, which would equate to a total of approximately two hours of transit time based on a vessel speed of approximately 4.5 kt (5.1 mph), would be de minimis, based on the fact that the use of these sources may occur for only a portion of the 10 nm of transit, resulting in a relatively brief amount of time that these sources would potentially be operating in the absence of airgun operation. Additionally, as the take estimate methodology (see Estimated Take by Incidental Harassment) includes a 25 percent contingency for equipment failures, resurveys, or other operational needs, any takes that could potentially occur as a result of the MBES and SBP use in the absence of airgun operations would be accounted for in this 25 percent contingency.

As described above, NMFS considers the probability for entanglement of marine mammals to be so low as to be discountable, because of the vessel speed and the monitoring efforts onboard the survey vessel. Therefore, NMFS does not authorize additional takes for entanglement.

As described above, the *Langseth* will operate at a relatively slow speed (typically 4.6 knots [8.5 km/h; 5.3 mph]) when conducting the survey. Protected species observers would monitor for marine mammals, which would trigger mitigation measures, including vessel avoidance where safe. Therefore, NMFS does not anticipate nor do we authorize takes of marine mammals as a result of vessel strike.

There is no evidence that the planned survey activities could result in serious injury or mortality within the specified geographic area for the requested Authorization. The required mitigation and monitoring measures would minimize any potential risk for serious injury or mortality.

Analysis and Determinations

Negligible Impact

Negligible impact is "an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival" (50 CFR 216.103). The lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population level effects) forms the basis of a negligible impact finding. Thus, an estimate of the number of takes, alone, is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be "taken" through behavioral harassment, NMFS must consider other factors, such as the likely nature of any responses (their intensity, duration, etc.), the context of any responses (critical reproductive time or location, migration, etc.), as well as the number and nature of estimated Level A harassment takes, the number of estimated mortalities, effects on habitat, and the status of the species.

In making a negligible impact determination, NMFS considers:

- The number of anticipated injuries, serious injuries, or mortalities;
- The number, nature, and intensity, and duration of harassment; and
- The context in which the takes occur (*e.g.,* impacts to times or areas of significance);
- The status of stock or species of marine mammals (*i.e.,* depleted, not depleted, decreasing, increasing, stable, impact relative to the size of the population);
- Impacts on habitat affecting rates of recruitment/survival; and
- The effectiveness of monitoring and mitigation measures to reduce the number or severity of incidental takes.

To avoid repetition, our analysis applies to all the species listed in Table 7, given that NMFS expects the anticipated effects of the seismic airguns to be similar in nature. Where there are meaningful differences between species or stocks, or groups of species, in anticipated individual responses to activities, impact of expected take on the population due to differences in population status, or impacts on habitat, NMFS has identified species-specific factors to inform the analysis.

Given the required mitigation and related monitoring, NMFS does not anticipate that serious injury or mortality would occur as a result of Lamont-Doherty's seismic survey in the southeast Pacific Ocean. Thus NMFS does not authorize any mortality. NMFS's predicted estimates for Level A harassment take for some species are likely overestimates of the injury that will occur, as NMFS expects that successful implementation of the mitigation measures would avoid Level A take in some instances. Also, NMFS expects that some individuals would avoid the source at levels expected to result in injury, given sufficient notice of the *Langseth's* approach due to the vessel's relatively low speed when conducting seismic surveys. Though NMFS expects that Level A harassment is unlikely to occur at the numbers authorized, is difficult to quantify the degree to which the mitigation and avoidance will reduce the number of animals that might incur PTS, therefore we authorize, include in our analyses, the modeled number of Level A takes, which does not take the mitigation or avoidance into consideration. However, because of the constant movement of the *Langseth* and of the animals, as well as the fact that the vessel is not expected to remain in any one area in which individuals would be expected to concentrate for any extended amount of time (*i.e.,* since the duration of exposure to loud sounds will be relatively short), we anticipate that any PTS that may be incurred in marine mammals would be in the form of only a small degree of permanent threshold shift, and not total deafness, that would not be likely to affect the fitness of any individuals.

Of the marine mammal species under our jurisdiction that are known to occur or likely to occur in the study area, the following species are listed as endangered under the ESA: Blue, fin, humpback, sei, Southern right, and sperm whales. The other marine mammal species that may be taken by harassment during Lamont-Doherty's seismic survey program are not listed as threatened or endangered under the ESA.

Cetaceans. Odontocete reactions to seismic energy pulses are usually thought to be limited to shorter distances from the airgun(s) than are those of mysticetes, in part because odontocete low-frequency hearing is assumed to be less sensitive to the low frequency signals of these airguns than that of mysticetes. NMFS generally expects cetaceans to move away from a noise source that is annoying prior to its becoming potentially injurious, and this expectation is expected to hold true in the case of the planned activities, especially given the relatively slow travel speed of the *Langseth* while seismic surveys are being conducted (4.5 kt; 5.1 mph). The relatively slow ship speed is expected to provide cetaceans with sufficient notice of the oncoming vessel and thus sufficient opportunity to avoid the seismic sound source before it reaches a level that would be potentially injurious to the animal. However, as described above, Level A takes for a small group of cetacean species are authorized.

Potential impacts to marine mammal habitat were discussed previously in this document (see the "Anticipated Effects on Habitat" section). Although some disturbance is possible to food sources of marine mammals, the impacts are anticipated to be minor enough as to not affect the feeding success of any individuals long-term. Regarding direct effects on cetacean feeding, based on the fact that the action footprint does not include any areas recognized specifically for higher value feeding habitat, the mobile and ephemeral nature of most prey sources, and the size of the southeast Pacific Ocean where feeding by marine mammals occurs versus the localized area of the marine survey activities, any missed feeding opportunities in the direct project area are expected to be minor based on the fact that other equally valuable feeding opportunities likely exist nearby.

Taking into account the planned mitigation measures, effects on cetaceans are generally expected to be restricted to avoidance of a limited area around the survey operation and short-term changes in behavior, falling within the MMPA definition of "Level B harassment." Animals are not expected to permanently abandon any area that is surveyed, and based on the best available information, any behaviors that are interrupted during the activity are expected to resume once the activity ceases. For example, as described above, gray whales have continued to migrate annually along the west coast of North America with substantial increases in the population over recent years, despite intermittent seismic exploration in that area for decades (Appendix A in Malme *et al.,* 1984; Richardson *et al.,* 1995; Allen and Angliss, 2014). Similarly, bowhead whales have continued to travel to the eastern Beaufort Sea each summer, and their numbers have increased notably, despite seismic exploration in their summer and autumn range for many years (Richardson *et al.,* 1987; Allen and Angliss, 2014). The history of coexistence between seismic surveys and baleen whales suggests that brief exposures to sound pulses from any single seismic survey are unlikely to result in prolonged effects. Only a small portion of marine mammal habitat will be affected at any time, and other areas within the southeast Pacific Ocean would be available for necessary biological functions. Overall, the consequences of behavioral modification are not expected to affect cetacean growth, survival, and/or reproduction, and therefore are not expected to be biologically significant.

Pinnipeds. Generally speaking, pinnipeds may react to a sound source in a number of ways depending on their experience with the sound source and what activity they are engaged in at the time of the exposure, with behavioral responses to sound ranging from a mild orienting response, or a shifting of attention, to flight and panic. However, research and monitoring observations from activities similar to those planned have shown that pinnipeds in the water are generally tolerant of anthropogenic noise and activity. Visual monitoring from seismic vessels has shown only slight (if any) avoidance of airguns by pinnipeds and only slight (if any) changes in behavior (Harris *et al.,* 2001; Moulton and Lawson, 2002). During foraging trips, extralimital pinnipeds may not react at all to the sound from the survey or may alert, ignore the stimulus, change their behavior, or avoid the immediate area by swimming away or diving. Behavioral effects to sound are generally more likely to occur at higher received levels (*i.e.,* within a few kilometers of a sound source). However, the slow speed of the *Langseth* while conducting seismic surveys (approximately 4.5 kt; 5.1 mph) is expected to provide ample opportunity for pinnipeds to avoid and keep some distance between themselves and the loudest sources of sound associated with the planned activities. Additionally, underwater sound from the planned survey would not be audible at pinniped haulouts or rookeries, therefore the consequences of behavioral responses in these areas are expected to be minimal. Overall, the consequences of behavioral modification are not expected to affect pinniped growth, survival, and/or reproduction, and therefore are not expected to be biologically significant.

Many animals perform vital functions, such as feeding, resting, traveling, and socializing, on a diel cycle (*i.e.,* 24 hour cycle). Behavioral reactions to noise exposure (such as disruption of critical life functions, displacement, or avoidance of important habitat) are more likely to be significant if they last more than one diel cycle or recur on subsequent days (Southall *et al.,* 2007). While NMFS anticipates that the seismic operations would occur on consecutive days, the estimated duration of the survey would last no more than 75 days but would increase sound levels in the marine environment in a relatively small area surrounding the vessel (compared to the range of most of the marine mammals within the survey area), which is constantly travelling over distances, and some animals may only be exposed to and harassed by sound for less than a day.

For reasons stated previously in this document and based on the following factors, Lamont-Doherty's planned activities are not likely to cause long-term behavioral disturbance, serious injury, or death, or other effects that would be expected to adversely affect reproduction or survival of any individuals. They include:

- The anticipated impacts of Lamont-Doherty's survey activities on marine mammals are temporary behavioral changes due, primarily, to avoidance of the area around the seismic vessel;
- The likelihood that, given the constant movement of boat and animals and the nature of the survey design (not concentrated in areas of high marine mammal concentration), any PTS that is incurred would be of a low level;
- The availability of alternate areas of similar habitat value for marine mammals to temporarily vacate the survey area during the operation of the airgun(s) to avoid acoustic harassment;
- The expectation that the seismic survey would have no more than a temporary and minimal adverse effect on any fish or invertebrate species that serve as prey species for marine mammals, and therefore consider the potential impacts to marine mammal habitat minimal.

Tables 4–7 in this document describe the number of Level A and Level B harassment takes that we anticipate as a result of the planned survey activities outside Chile's territorial sea (12 nm). Lamont-Doherty would conduct the planned seismic survey within the EEZ and territorial waters of Chile. The planned survey would occur primarily on the high seas, with a small portion occurring within Chile's territorial sea. As described above, NMFS does not have authority to authorize the incidental take of marine mammals in the territorial seas of foreign nations, because the MMPA does not apply in those waters. However, as part of the analysis supporting our determination under the MMPA that the activity would have a negligible impact on the affected species, we must consider the incidental take expected to occur as a result of the activity in the entire activity area, including both territorial seas and high seas.

Based on NMFS's analysis, the area within the planned northern survey predicted to be ensonified to the Level B harassment threshold (160 dB re: 1 μPa) within Chilean territorial seas accounts for approximately 19 percent of the total area (including high seas and Chilean territorial seas combined) predicted to be ensonified to the Level B harassment threshold; for the planned central survey, the area predicted to be ensonified to the Level B harassment threshold within territorial seas accounts for approximately three percent of the total area predicted to be ensonified to the Level B harassment threshold in that entire survey area; and for the planned southern survey, the area predicted to be ensonified to the Level B harassment threshold within territorial seas accounts for approximately 24 percent of the total area predicted to be ensonified to the Level B harassment threshold in that entire survey area (Table 8).

We expect the impacts of Lamont-Doherty's survey activities, including the impacts of takes that are expected to occur within the territorial sea, to include temporary behavioral changes due, primarily, to avoidance of the area around the seismic vessel, with the potential for a small degree of PTS in a limited number of animals. Effects on marine mammals are generally expected to be restricted to avoidance of a limited area around the survey operation and short-term changes in behavior, falling within the MMPA definition of "Level B harassment." The slow speed of the *Langseth* while conducting seismic surveys (approximately 4.5 kt; 5.1 mph) is expected to provide ample opportunity for pinnipeds and cetaceans to avoid and keep some distance between themselves and the loudest sources of sound associated with the planned activities, both within and outside the territorial sea. Additionally, underwater sound from the planned survey, including the portions of the survey planned within the territorial sea, would not be audible at pinniped haulouts or rookeries, therefore the consequences of behavioral responses in these areas are expected to be minimal. Overall, taking into account the takes expected to occur within the territorial sea as well as those expected to occur outside the territorial sea that NMFS authorizes, the consequences of behavioral modification are not expected to affect growth, survival, and/or reproduction of cetaceans or pinnipeds, and therefore are not expected to be biologically significant.

Marine mammals are not expected to permanently abandon any area that is surveyed, including areas within territorial seas, and based on the best available information, any behaviors that are interrupted during the activity are expected to resume once the activity ceases. Although some disturbance is possible to food sources of marine mammals within territorial seas, the impacts to those marine mammals are anticipated to be minor enough as to not affect the feeding success of any individuals long-term. Any missed feeding opportunities in the project area within territorial seas are expected to be minor based on the fact that other equally valuable feeding opportunities likely exist nearby. The portions of the seismic surveys that will occur within territorial seas would have no more than a temporary and minimal adverse effect on any fish or invertebrate species that serve as prey species for marine mammals, and therefore we believe the potential impacts to marine mammal habitat will be minimal.

As is the case for surveys outside territorial seas as described above, due to constant movement of the *Langseth* and of the animals, as well as the fact that the vessel is not expected to remain in any one area in which individuals would be expected to concentrate for any extended amount of time (*i.e.,* since the duration of exposure to loud sounds will be relatively short), we anticipate that any PTS that may be incurred in marine mammals within the territorial sea would be in the form of only a small degree of permanent threshold shift, and not total deafness, that would not be likely to affect the fitness of any individuals. There is no evidence that the planned survey activities, either outside or within the territorial sea, could result in serious injury or mortality of marine mammals, and as described above NMFS expects that individuals would avoid the source at levels expected to result in injury, given sufficient notice of the *Langseth's* approach due to the vessel's relatively low speed when conducting seismic surveys.

For the reasons described above, the takes that would occur within the territorial sea, while not authorized by NMFS,do not alter our determinations above with respect to the relative likelihood of the activity to cause long-term behavioral disturbance, serious injury, or death, or other effects that would be expected to adversely affect reproduction or survival of any individual marine mammals.

TABLE 8—AREAS PREDICTED TO BE ENSONIFIED TO LEVEL B HARASSMENT THRESHOLD INSIDE AND OUTSIDE CHILEAN TERRITORIAL SEAS, AND PERCENT INCREASE IN ENSONIFIED AREA PREDICTED IN TERRITORIAL SEAS VERSUS ENSONIFIED AREA PREDICTED OUTSIDE TERRITORIAL SEAS

Planned survey location	Total area ensonified to Level B harassment threshold (160 dB re: 1 μPa)	Area ensonified to Level B harassment threshold (160 dB re: 1 μPa) outside territorial seas (percentage of total ensonified area in survey location)	Area ensonified to Level B harassment threshold (160 dB re: 1 μPa) inside territorial seas (percentage of total ensonified area in survey location)	Percent increase in ensonified area when territorial sea is included in survey area
Northern	61,295 km^2	49,645 km^2 (81%)	11,650 km^2 (19%)	23%
Central	10,593 km^2	10,315 km^2 (97.4%)	278 km^2 (2.6%)	3
Southern	76,449 km^2	58,117 km^2 (76%)	18,332 km^2 (24%)	32

Required mitigation measures, such as special shutdowns for large whales, vessel speed, course alteration, and visual monitoring would be implemented to help reduce impacts to marine mammals. Based on the analysis herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the monitoring and mitigation measures, NMFS finds that Lamont-Doherty's planned seismic survey would have a negligible impact on the affected marine mammal species or stocks.

Small Numbers

As described previously, NMFS estimates that Lamont-Doherty's activities could potentially affect, by Level B harassment, 44 species of marine mammals under our jurisdiction. NMFS estimates that Lamont-Doherty's activities could potentially affect, by Level A harassment, up to 26 species of marine mammals under our jurisdiction.

For each species, the numbers of take authorized are small relative to the population sizes: Less than 18 percent for South American sea lion, less than 15 percent for the dusky dolphin, less than 11.5 percent for Chilean dolphin, and less than 5 percent for all other species (Table 7). As described above, NMFS cannot authorize the incidental take of marine mammals in the territorial seas of foreign nations, but must consider the level of incidental take as a result of the activity in the entire activity area (including both territorial seas and high seas) as part of the analysis supporting our determination under the MMPA that the activity would have a negligible impact on the affected species. We assume for the purposes of our analysis that the take predicted to occur within the Chilean territorial sea will account for approximately a 23 percent increase in the northern survey area; a 3 percent increase in the central survey area; and a 32 percent increase in the southern survey area, compared to the total number of incidental takes predicted to occur outside of the Chilean territorial sea (Table 7 and Table 8). Accounting for these additional takes, the total takes predicted to result from the planned survey (including both the takes authorized by NMFS and the takes not authorized by NMFS but predicted to occur within the Chilean territorial sea) are still small relative to the population sizes, with no more than 22 percent taken for any marine mammal species.

NMFS is not aware of reliable abundance estimates for four species of marine mammals (Burmeister's porpoise, Peale's dolphin, pygmy right whale, and southern right whale dolphin) for which incidental take is authorized. Therefore we rely on the best available information on these species to make determinations as to whether the authorized take numbers represent small numbers of the total populations of these species.

The Burmeister's porpoise is distributed from the Atlantic Ocean in southern Brazil to the Pacific Ocean in northern Peru (Reyes 2009). While there are no quantitative data on abundance, the best available information suggest the species is assumed to be numerous throughout South American coastal waters (Brownell Jr. and Clapham 1999), with groups estimated at approximately 150 individuals observed off of Peru (Van Waerebeek *et al.* 2002). In addition the species is typically found shoreward of the 60 m isobath (Hammond *et al.* 2012), suggesting that the number of authorized takes is likely conservative as the species is unlikely to be encountered throughout the full survey area. The species' wide distribution and apparent abundance suggest the number of authorized takes represents a small number of individuals relative to the species' total abundance.

Peale's dolphin is a coastal species that is known to inhabit waters very near to shore, commonly within or shoreward of kelp beds, while in the waters of southern Chile and Tierra del Fuego they appear to prefer channels, fjords and deep bays (Goodall 2009). Their apparent habitat preference for waters very near to shore suggests that the number of authorized takes is likely very conservative as the species is unlikely to be encountered throughout much of the survey area. While no abundance estimate exists for the species, Peale's dolphin is reportedly the most common cetacean found around the coast of the Falkland Islands and Chile *(Brownell Jr. et al.* 1999). The combination of the species' apparent abundance and the species' apparent preference for habitats that would not be surveyed by Lamont-Doherty suggests the number of authorized takes represents a small number of individuals relative to the species' total abundance.

The full distribution of the southern right whale dolphin is not known, but the species appears to be circumpolar and fairly common throughout its range. Survey data and stranding and fishery interaction data in northern Chile suggest that the species may be one of the most common cetaceans in the region (Van Waerebeek et al. 1991). The species' apparent abundance and its broad distribution suggest the number of authorized takes represents a small number of individuals relative to the species' total abundance.

The pygmy right whale has a circumpolar distribution, between about 30° and 55°S, with records from southern South America as well as Africa, Australia and New Zealand (Kemper 2009). There are no estimates of abundance for the species, but judging by the number of strandings in Australia and New Zealand, it is likely to be reasonably common in that region (Kemper 2009), with aggregations of up to approximately 80 individuals reported (Matsuoka 1996). The species' apparent abundance and its broad distribution suggest the number of authorized takes would represent a small number of individuals relative to the species' total abundance.

NMFS finds that the incidental take associated with Lamont-Doherty's planned seismic survey would be limited to small numbers relative to the affected species or stocks.

Impact on Availability of Affected Species or Stock for Taking for Subsistence Uses

There are no relevant subsistence uses of marine mammals implicated by this action.

Endangered Species Act (ESA)

There are six marine mammal species listed as endangered under the Endangered Species Act that may occur in the survey area. Under section 7 of the ESA, NSF initiated formal consultation with the NMFS Office of Protected Resources (OPR) Endangered Species Act Interagency Cooperation Division on the planned seismic survey. We (the NMFS Office of Protected Resources, Permits and Conservation Division) also consulted internally under section 7 of the ESA with the NMFS OPR Endangered Species Act Interagency Cooperation Division on the issuance of an Authorization under section 101(a)(5)(D) of the MMPA.

In July, 2016, the NMFS OPR Endangered Species Act Interagency Cooperation Division issued a Biological Opinion with an Incidental Take Statement to us and to the NSF, which concluded that the issuance of the Authorization and the conduct of the seismic survey were not likely to jeopardize the continued existence of blue, fin, humpback, sei, Southern right and sperm whales. The Biological Opinion also concluded that the issuance of the Authorization and the conduct of the seismic survey would not affect designated critical habitat for these species.

National Environmental Policy Act (NEPA)

NSF prepared an environmental analysis titled, "*Environmental Analysis of a Marine Geophysical Survey by the R/V Marcus G. Langseth in the Southeast Pacific Ocean, 2016/2017*". NMFS independently evaluated the environmental analysis and prepared an Environmental Assessment (EA) titled, "*Proposed Issuance of an Incidental Harassment Authorization to Lamont-Doherty Earth Observatory to Take Marine Mammals by Harassment Incidental to a Marine Geophysical Survey in the Southeast Pacific Ocean, 2016/2017*". NMFS and NSF provided relevant environmental information to the public through the **Federal Register** notice for the proposed IHA (81 FR 23117; April 19, 2016) and considered public comments received prior to finalizing our EA and deciding whether or not to issue a Finding of No Significant Impact (FONSI). NMFS concluded that issuance of an IHA to Lamont-Doherty would not significantly affect the quality of the human environment and prepared and issued a FONSI in accordance with NEPA and NOAA Administrative Order 216–6. NMFS's EA and FONSI for this activity are available on our Web site at: *http://www.nmfs.noaa.gov/pr/permits/incidental.*

Authorization

NMFS has issued an Authorization to Lamont-Doherty for the potential harassment of small numbers of 44 marine mammal species incidental to conducting a seismic survey in the Southeast Pacific Ocean, between August 1, 2016 and July 31, 2017, provided the previously mentioned mitigation, monitoring and reporting measures.

Dated: August 8, 2016.

Donna Wieting,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2016–19145 Filed 8–11–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE799

New England Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a joint public meeting of its Monkfish Committee on Thursday, September 1, 2016 to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Thursday, September 1, 2016 at 9:30 a.m.

ADDRESSES:

Meeting address: The meeting will be held at the Radisson Airport Hotel, 2081 Post Road, Warwick, RI 02886; telephone: (401) 739–3000; fax: (401) 732–9309.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION: The Monkfish Committee will meet to receive a report on the 2016 operational assessment. The Committee will discuss the Scientific and Statistical Committee recommendations for Allowable Biological Catch (ABC) for FYs 2017–19, the potential range of alternatives for the specifications package, and priorities for 2017. There will be a closed session to review advisory panel applications. The Committee will discuss other business, as needed.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at 978–465–0492, at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 9, 2016.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–19252 Filed 8–11–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE730

Pacific Island Fisheries; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; public meeting.

SUMMARY: NMFS announces a Western Pacific Stock Assessment Review of the report "Stock Assessment of the Coral Reef Fishes of Hawaii, 2016." The report contains single-species stock assessments for 28 species of reef-associated fish stocks around the main Hawaiian islands. A panel of three independent experts will review the stock assessment and report their findings.

DATES: See the **SUPPLEMENTARY INFORMATION** section for meeting dates and times.

ADDRESSES: The meeting will be held in Suite 1701, Finance Factors Building, 1164 Bishop St., Honolulu, HI 96813.

FOR FURTHER INFORMATION CONTACT: Matt Dunlap, NMFS Pacific Islands Regional Office, (808) 725–5177 or *matthew.dunlap@noaa.gov.*

SUPPLEMENTARY INFORMATION: The meeting schedule and agenda are as follows (8:30 a.m.–5 p.m. every day):

Monday, August 29, 2016

- Introductions
- Background information
- Objectives and Terms of Reference
- Fishery Operation
- Management
- Presentation of stock assessments (Nadon)

Tuesday, August 30, 2016

- Presentation and review of stock assessments (Nadon and Panel)

Wednesday, August 31, 2016

- Continue review of stock assessments (Nadon and Panel)

Thursday, September 1, 2016

- Continue review of stock assessments
- Public comment period
- Panel discussion (closed)

Friday, September 2, 2016

- Panel discussions (morning, closed)
- Present results of review and recommendations (afternoon, open)
- Adjourn

The agenda order may change. The meeting will run as late as necessary to complete scheduled business. Although non-emergency issues that are not contained in this agenda may come up at the meeting for discussion, those issues may not be the subject of formal action during the meeting. Action will be restricted to those issues specifically listed in this notice, and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Make direct requests for sign language interpretation or other auxiliary aids to Matt Dunlap, (808) 725–5177 or *matthew.dunlap@noaa.gov,* at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 9, 2016.

Emily H. Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–19253 Filed 8–11–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE798

New England Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Groundfish Advisory Panel to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Tuesday, August 30, 2016 at 10 a.m.

ADDRESSES: The meeting will be held at the DoubleTree by Hilton, 50 Ferncroft Road, Danvers, MA 01950; phone: (978) 777–2500; fax: (978) 750–7911.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Advisory Panel will review the draft alternatives for Framework Adjustment 56 (specifications and management measures) and make recommendations to the Groundfish Committee. They will discuss and summarize recent market and fishery information regarding groundfish stocks—focusing on those with assessments this year (*i.e.,* Eastern

Georges Bank cod, Eastern Georges Bank haddock, Georges Bank yellowtail flounder, and witch flounder). The Panel will also discuss the Plan Development Team's draft white paper on monitoring strategies and make recommendations to the Groundfish Committee. They will discuss and summarize perspectives on the 2010–11 dockside monitoring program. They will also discuss make recommendations to the Groundfish Committee on priorities for 2017. Other business will be discussed as necessary.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during these meetings. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 9, 2016.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–19251 Filed 8–11–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Paperwork Submissions Under the Coastal Zone Management Act Federal Consistency Requirements.

OMB Control Number: 0648–0411.

Form Number(s): None.

Type of Request: Regular (extension of a currently approved information collection).

Number of Respondents: 2,334.

Average Hours per Response: Applications/certifications and state preparation of objection or concurrence letters, 8 hours each ; state requests for review of unlisted activities, 4 hours; public notices, 1 hours; remedial action and supplemental review, 6 hours; listing notices, 1 hour; interstate listing notices, 30 hours; mediation, 2 hours; appeals to the Secretary of Commerce, 210 hours.

Burden Hours: 35,799.

Needs and Uses: This request is for extension of a currently approved information collection.

A number of paperwork submissions are required by the Coastal Zone Management Act (CZMA) federal consistency provision, 16 U.S.C. 1456, and by NOAA to provide a reasonable, efficient and predictable means of complying with CZMA requirements. The requirements are detailed in 15 CFR part 930. The information will be used by coastal states with federally-approved Coastal Zone Management Programs to determine if Federal agency activities, Federal license or permit activities, and Federal assistance activities that affect a state's coastal zone are consistent with the states' programs. Information will also be used by NOAA and the Secretary of Commerce for appeals to the Secretary by non-federal applicants regarding State CZMA objections to federal license or permit activities.

Affected Public: State, local or tribal government; business or other for-profit organizations; individuals or households.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain benefits.

This information collection request may be viewed at *reginfo.gov.* Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Dated: August 8, 2016.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2016–19157 Filed 8–11–16; 8:45 am]

BILLING CODE 3510–08–P

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

BroadbandUSA Webinar Series

AGENCY: National Telecommunications and Information Administration, U.S. Department of Commerce.

ACTION: Notice of Open Meetings—Monthly Webinars.

SUMMARY: The National Telecommunications and Information Administration (NTIA), as part of its BroadbandUSA program, will host a series of webinars on a monthly basis to engage the public and stakeholders with information to accelerate broadband access, improve digital inclusion, strengthen broadband policies, and support local community priorities. The webinar series will provide an ongoing source of information on the range of topics and issues being addressed by BroadbandUSA, including best practices for improving broadband deployment, digital literacy, and e-government.

The webinars will be held on the third Wednesday of every month, beginning August 17, 2016 and continuing through January 19, 2017. Details on specific webinar topics and webinar registration information will be posted on the BroadbandUSA Web site *http://www2.ntia.doc.gov/* under *Events.* Powerpoint slides and transcripts of the webinars will be posted on the Web site within seven days following the live webinar.

DATES: BroadbandUSA will hold the webinars from 2:00 p.m. to 3:00 p.m. Eastern Time on the third Wednesday of every month, beginning August 17, 2016 and continuing through January 18, 2017.

ADDRESSES: This is a virtual meeting. NTIA will post the registration information on its BroadbandUSA Web site *http://www2.ntia.doc.gov/* under *Events.*

FOR FURTHER INFORMATION CONTACT: Lynn Chadwick, National Telecommunications and Information Administration, U.S. Department of Commerce, Room 4627, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–8338; email: *lchadwick@ntia.doc.gov.* Please direct media inquiries to NTIA's Office of Public Affairs, (202) 482–7002; email *press@ntia.doc.gov.*

SUPPLEMENTARY INFORMATION: NTIA's BroadbandUSA program provides expert advice and field-proven tools for assessing broadband adoption, planning new infrastructure, and engaging a wide range of partners in broadband projects. BroadbandUSA convenes workshops on a regular basis to bring stakeholders together to discuss ways to improve broadband policies, share best practices, and connect communities to other federal agencies and funding sources for the purpose of expanding broadband infrastructure and adoption throughout America's communities. Experts from NTIA's BroadbandUSA program are available to provide technical assistance and to connect communities with additional resources, such as best practices, guides and program models.

NTIA's BroadbandUSA team is developing tools to support communities working to expand broadband access, adoption, and use. These webinars are among the tools BroadbandUSA uses to provide broadband information to the public, stakeholders, tribal, local, and state governments, and federal programs. Other tools include publications, workshops, meetings and co-hosted events with stakeholder organizations and agencies.

Participants are welcome to view one or many webinars. General questions and comments are welcome at any time during webinars via email to *BroadbandUSA@ntia.doc.gov.* The webinars are open to the public and press. Pre-registration is recommended. NTIA asks registrants to provide their first and last names and email addresses for both registration purposes and to receive any updates on BroadbandUSA or via email at *BroadbandUSA@ntia.doc.gov.* Meeting agendas and relevant documents, including information on how to register for one or more webinars, will be also available on NTIA's Web site at *http://www2.ntia.doc.gov/WEBINARS.* Individuals requiring accommodations should review the transcript and Powerpoint slides from the webinar posted at the BroadbandUSA Web site, *http://www2.ntia.doc.gov/* within seven days following the live webinar.

Dated: August 8, 2016.

Milton Brown,

Deputy Chief Counsel, National Telecommunications and Information Administration.

[FR Doc. 2016–19149 Filed 8–11–16; 8:45 am]

BILLING CODE 3510–60–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed deletions from the Procurement List.

SUMMARY: The Committee is proposing to delete products and services from the Procurement List that were previously furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: Comments must be received on or before September 11, 2016.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia, 22202–4149.

FOR FURTHER INFORMATION CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Deletions

The following products and services are proposed for deletion from the Procurement List:

Products

NSN(s)—Product Name(s): 2540–01–071–2051—Cover, Cushion Assembly
Mandatory Source(s) of Supply: Pioneer Vocational/Industrial Services, Inc., Danville, KY
Contracting Activity: Defense Logistics Agency Land and Maritime
NSN(s)—Product Name(s):
  7530–01–071–9792—Paper, Bond, Dual Purpose, Opaque Buff, 8.5″ x 11″
  7530–01–148–1766—Paper, Xerographic, Dual Purpose, Buff, 8.5″ x 11″
Mandatory Source(s) of Supply: Louisiana Association for the Blind, Shreveport, LA
Contracting Activity: General Services Administration, New York, NY
NSN(s)—Product Name(s): 6540–01–131–7919—Case, Spectacles
Mandatory Source(s) of Supply: Dallas Lighthouse for the Blind, Inc., Dallas, TX
Contracting Activity: Defense Logistics Agency Troop Support

Services

Service Types:
  Administrative Service
  Laundry Service
  Food Service Attendant Service
Mandatory for: Department of Veterans Affairs, James A. Quillen VA Medical Center, Mountain Home, TN
Mandatory Source(s) of Supply: Dawn of Hope, Inc., Johnson City, TN
Contracting Activity: Department of Veterans Affairs

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2016–19235 Filed 8–11–16; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to and Deletions from the Procurement List.

SUMMARY: This action adds products and services to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes services from the Procurement List previously furnished by such agencies.

DATES: Effective on September 11, 2016.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Additions

On 6/17/2016 (81 FR 39630) and 7/8/2016 (81 FR 44597), the Committee for Purchase From People Who Are Blind or Severely Disabled published notices of proposed additions to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the products and services and impact of the additions on the current or most recent contractors, the Committee has determined that the products and services listed below are suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the products and services to the Government.

2. The action will result in authorizing small entities to furnish the products and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the products and services proposed for addition to the Procurement List.

End of Certification

Accordingly, the following products and services are added to the Procurement List:

Products

NSN(s)—Product Name(s): MR 753—Pillow, Jumbo
Mandatory for: Military commissaries and exchanges in accordance with the Code of Federal Regulations, Chapter 51, 51–6.4.
Mandatory Source(s) of Supply: Georgia Industries for the Blind, Bainbridge, GA
Contracting Activity: Defense Commissary Agency
Distribution: C-List
NSN(s)—Product Name(s)
  7930–00–NIB–0578—Disinfectant 256 Cleaner, Neutral, Concentrated, High Dilution
  7930–00–NIB–0579—Disinfectant PD–128 Cleaner, Intermediate, Broad Spectrum, Concentrated
  8125–00–NIB–0031—Spray Bottle, High Dilution 256 Neutral Disinfectant, 32 oz. Bottle
  8125–00–NIB–0032—Spray Bottle, PD–128 Disinfectant Cleaner, 32 oz. Bottle
Mandatory for: Department of Veterans Affairs
Mandatory Source of Supply: VisionCorps, Lancaster, PA
Contracting Activity: Department of Veterans Affairs, Strategic Acquisition Center, Fredericksburg, VA
Distribution: C-List

Services

Service Type: Janitorial Service
Mandatory for: USDA APHIS, Luis Munoz Marin Airport, Terminal A & D, 150 Central Sector, Carolina, PR
Mandatory Source(s) of Supply: The Corporate Source, Inc., New York, NY
Contracting Activity: Dept of Agriculture, USDA APHIS MRPBS, Animal and Plant Health Inspection Service, Minneapolis, MN
Service Type: Mailroom Operation Service
Mandatory for: US Air Force, Postal Service Center, Tyndall Air Force Base, Tyndall Air Force, FL
Mandatory Source(s) of Supply: VersAbility, Resources, Inc., Hampton, VA
Contracting Activity: Dept of the Air Force, FA4890 ACC AMIC, Newport News, VA

Deletions

On 7/8/2016 (81 FR 44597), the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed deletions from the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the services listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the services deleted from the Procurement List.

End of Certification

Accordingly, the following services are deleted from the Procurement List:

Services

Service Type: Order Processing Service
Mandatory for: McGuire Air Force Base, McGuire AFB, NJ
Mandatory Source(s) of Supply: Bestwork Industries for the Blind, Inc., Cherry Hill, NJ
Contracting Activity: Dept of the Air Force, FA7014 AFDW PK
Service Type: Operation of Postal Service Center Service
Mandatory for: Luke Air Force Base, Glendale, AZ
Mandatory Source(s) of Supply: Arizona Industries for the Blind, Phoenix, AZ
Contracting Activity: Dept of the Air Force, FA7014 AFDW PK
Service Type: Telephone Switchboard Operations Service
Mandatory for: Barksdale Air Force Base, Shreveport, LA
Mandatory Source(s) of Supply: Louisiana Association for the Blind, Shreveport, LA
Contracting Activity: Dept of the Air Force, FA7014 AFDW PK
Service Type: Embroidery of USAF Service Name Tapes & Emboss of Plastic Name Tags Base
Mandatory for: Lackland Air Force Base, San Antonio, TX
Mandatory Source(s) of Supply: Delaware Division for the Visually Impaired, New Castle, DE
Contracting Activity: Dept of the Air Force, FA7014 AFDW PK

Barry S. Lineback,
Director, Business Operations.

[FR Doc. 2016–19236 Filed 8–11–16; 8:45 am]
BILLING CODE 6353–01–P

COMMODITY FUTURES TRADING COMMISSION

Order Exempting the Federal Reserve Banks From Sections 4d and 22 of the Commodity Exchange Act

AGENCY: Commodity Futures Trading Commission.

ACTION: Order.

SUMMARY: The Commodity Futures Trading Commission ("CFTC" or "Commission") is issuing an order to exempt Federal Reserve Banks that provide customer accounts and other services to registered derivatives clearing organizations that are designated financial market utilities from Sections 4d and 22 of the Commodity Exchange Act ("CEA").

DATES: *Effective Date:* August 8, 2016.

FOR FURTHER INFORMATION CONTACT: Eileen A. Donovan, Deputy Director, 202–418–5096, *edonovan@cftc.gov;* M. Laura Astrada, Associate Director, 202–418–7622, *lastrada@cftc.gov;* or Parisa Abadi, Attorney-Advisor, 202–418–6620, *pabadi@cftc.gov,* in each case, at the Division of Clearing and Risk, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581; or Joe Opron, Special Counsel, 312–596–0653, *jopron@cftc.gov,* Division of Clearing and Risk, Commodity Futures Trading Commission, 525 West Monroe Street, Suite 1100, Chicago, IL 60661.

SUPPLEMENTARY INFORMATION:

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I. Introduction

On June 2, 2016, the Commission published in the **Federal Register** a notice and request for public comment regarding a proposed Commission order that would exempt, pursuant to Section 4(c) of the CEA,[1] Federal Reserve Banks that provide customer accounts and other services to systemically important derivatives clearing organizations ("SIDCOs")[2] from Sections 4d and 22 of the CEA (the "Proposal").[3] After consideration of the comments and for the reasons set forth in the Proposal and in this release, the Commission is issuing an order that exempts, subject to certain conditions, Federal Reserve Banks that provide customer accounts and other services to designated financial market utilities ("FMUs") that are registered derivatives clearing organizations ("Designated FMUs")[4] from Sections 4d and 22 of the CEA. The exemption enables Federal Reserve Banks to maintain customer accounts for Designated FMUs in accordance with the standards set forth in the relevant Federal Reserve Bank governing documents, as specified below.

II. Background

A. Designation of FMUs Under Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act

Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act ("Dodd-Frank Act") was enacted to mitigate risk in the financial system and promote financial stability.[5] Accordingly, Section 804 of the Dodd-Frank Act requires the Financial Stability Oversight Council ("Council") to designate those FMUs that the Council determines are, or are likely to become, systemically important.[6] An FMU includes "any person that manages or operates a multilateral system for the purpose of transferring, clearing, or settling payments, securities, or other financial transactions among financial institutions or between financial institutions and the person."[7]

On July 18, 2012, the Council designated eight FMUs as systemically important under Title VIII.[8] Two of these systemically important FMUs, Chicago Mercantile Exchange, Inc. ("CME") and ICE Clear Credit LLC ("ICC"), are SIDCOs (and therefore, Designated FMUs). In addition, the Options Clearing Corporation ("OCC"), which is a registered derivatives clearing organization ("DCO") but not a SIDCO, is a Designated FMU. OCC was designated in its capacity as a securities clearing agency; the Securities and Exchange Commission is its Supervisory Agency.

B. Access to Federal Reserve Bank Accounts and Services

Section 806(a) of the Dodd-Frank Act permits the Board to authorize a Federal Reserve Bank to establish and maintain an account for a Designated FMU and provide to the Designated FMU the services listed in Section 11A(b) of the Federal Reserve Act, subject to any applicable rules, orders, standards, or guidelines prescribed by the Board.[9] In adopting regulations pursuant to Section 806(a) of the Dodd-Frank Act, the Board noted that the "terms and conditions for access to Federal Reserve Bank accounts and services are intended to facilitate the use of [Federal] Reserve Bank accounts and services by a designated FMU in order to reduce settlement risk and strengthen settlement processes, while limiting the risk presented by the designated FMU to the [Federal] Reserve Banks."[10] Accordingly, the Board "expects that [Federal] Reserve Banks would provide services that are consistent with a designated FMU's need for safe and sound settlement processes under account and service agreements generally consistent with the provisions of existing [Federal] Reserve Bank operating circulars for such services."[11] Highlighting the importance of Federal Reserve Bank operating circulars in this regard, the Board further requires that designated FMUs be in compliance with existing operating circulars.[12]

C. Proposed Order

The proposed Commission order would, subject to certain terms and conditions, exempt Federal Reserve Banks that provide customer accounts and other services to SIDCOs from Sections 4d and 22 of the CEA. In the Proposal, the Commission emphasized the importance of protecting customers and safeguarding customer funds, and highlighted the critical role that SIDCOs play in the financial markets. The Commission recognized that the failure of a SIDCO or a disruption to the operations of a SIDCO could threaten the stability of the U.S. financial system. As a result, the Commission determined that reducing SIDCOs' credit and liquidity risks would better protect market participants and the public, and would serve to promote the integrity of the financial markets. The Commission explained that because Federal Reserve Banks are the source of liquidity with regard to U.S. dollar deposits, a SIDCO would face much lower credit and liquidity risk with a deposit at a Federal Reserve Bank than it would with a deposit at a commercial bank.

With respect to protecting customers and safeguarding customer funds, the Commission explained that under Section 4d of the CEA, a depository will be held liable for an improper transfer of customer funds by an FCM or DCO if it knew or should have known that the transfer was improper.[13] The

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[1] 7 U.S.C. 6(c).

[2] Under Commission Regulation 39.2, a SIDCO is defined as a financial market utility that is a registered derivatives clearing organization under Section 5b of the CEA, which is currently designated by the Financial Stability Oversight Council to be systemically important, and for which the Commission acts as the Supervisory Agency pursuant to Section 803(8) of the Dodd-Frank Wall Street Reform and Consumer Protection Act. *See* 17 CFR 39.2. *See also* Section 803(8)(A) of the Dodd-Frank Act, which defines the term Supervisory Agency as the Federal agency that has primary jurisdiction over a designated financial market utility under Federal banking, securities, or commodity futures laws. Section 803(8)(A) of the Dodd-Frank Act, Pub. L. 111–203, 124 Stat. 1376 (2010).

[3] Notice of Proposed Order and Request for Comment on Proposal to Exempt, Pursuant to the Authority in Section 4(c) of the Commodity Exchange Act, the Federal Reserve Banks from Sections 4d and 22 of the Commodity Exchange Act, 81 FR 35337 (June 2, 2016).

[4] For the avoidance of doubt, the term "Designated FMU" includes the more narrow term "SIDCO."

[5] *See* Section 802(b) of the Dodd-Frank Act.

[6] *See* Section 804(a) of the Dodd-Frank Act. The term systemically important means a situation where the failure of or a disruption to the functioning of a financial market utility could create, or increase, the risk of significant liquidity or credit problems spreading among financial institutions or markets and thereby threaten the stability of the financial system of the United States. Section 803(9) of the Dodd-Frank Act; *see also* Authority to Designate Financial Market Utilities as Systemically Important, 76 FR 44763, 44774 (July 27, 2011).

[7] Section 803(6)(A) of the Dodd-Frank Act.

[8] *See* Press Release, Financial Stability Oversight Council, Financial Stability Oversight Council Makes First Designations in Effort to Protect Against Future Financial Crises (July 18, 2012), *available at http://www.treasury.gov/press-center/press-releases/Pages/tg1645.aspx.*

[9] The services listed in Section 11A(b) of the Federal Reserve Act include wire transfers, settlement, and securities safekeeping, as well as services regarding currency and coin, check clearing and collection, and automated clearing house transactions. *See* 12 U.S.C. 248a(b). Section 806(a) of the Dodd-Frank Act also permits the Board to authorize a Federal Reserve Bank to establish deposit accounts under the first undesignated paragraph of Section 13 of the Federal Reserve Act, 12 U.S.C. 342.

[10] Financial Market Utilities (Regulation HH), 78 FR 14024, 14025 (Mar. 4, 2013).

[11] *Id.*

[12] *See* 12 CFR 234.5(b)(2) (setting forth rules to govern Federal Reserve Bank accounts held by designated FMUs).

[13] *See* 81 FR at 35339. Further, the Commission requires a DCO to obtain from each depository with which it deposits customer funds a written acknowledgment that the customer funds are being

Commission noted, however, that as this standard of liability was developed, the unique nature of the Federal Reserve Banks was not taken into account.[14] The accounts and financial services provided by Federal Reserve Banks are governed by account agreements, operating circulars issued by Federal Reserve Banks for each service, the Federal Reserve Act, and Federal Reserve regulations and policies, and, with respect to book-entry securities services, the regulations of the domestic issuer of the securities or the issuer's regulator (''Federal Reserve Bank Governing Documents'').[15] In the Proposal, the Commission explained that the Federal Reserve Bank Governing Documents limit a Federal Reserve Bank's liability in maintaining an account or acting on such an instruction to actual damages that are incurred solely by the account holder and that are proximately caused by the Federal Reserve Bank's failure to exercise ordinary care or act in good faith in accordance with the Federal Reserve Bank Governing Documents. The Commission found the standard of liability as set forth in the Federal Reserve Bank Governing Documents to be appropriate in the context of Federal Reserve Banks, as this standard has been developed to more appropriately reflect the unique nature of the Federal Reserve Banks. Notably, the Commission argued that the Board has prescribed detailed rules and standards that govern account services provided to SIDCOs by the Federal Reserve Banks, which have been carefully developed to provide clarity surrounding the provision of Federal Reserve financial services and to promote consistency in the treatment of deposit accounts at the Federal Reserve Banks for the benefit of the U.S. financial system.[16]

The Commission noted its concern that exposing the Federal Reserve Banks to the standard of liability set forth in Section 4d of the CEA, as well as to potential third-party claims under Section 22 of the CEA,[17] could disrupt these goals and ultimately harm the U.S. financial system and, by extension, U.S. taxpayers. Accordingly, the Commission proposed that a Federal Reserve Bank acting as a depository for SIDCO customer funds or otherwise providing account services to a SIDCO would continue to be held to the standard of liability set forth in the Federal Reserve Bank Governing Documents.

However, the Commission reiterated the importance of the segregation requirements set forth in Section 4d of the CEA to make sure that customer funds are used only for the purpose of margining, securing, or guaranteeing their futures contracts and options on futures contracts, and cleared swaps. Therefore, as a condition to the proposed order, customer funds held at a Federal Reserve Bank would continue to be required to be segregated from the funds deposited in the SIDCO's proprietary account. In addition, Federal Reserve Banks would be required to reply promptly and directly to any request for confirmation of account balances or provision of any other information regarding or related to the customer account(s) of a SIDCO that are established pursuant to the CEA from the director of the Division of Clearing and Risk of the Commission, or any successor division, or such director's designees.

The Commission further noted that Title VIII of the Dodd-Frank Act permits a Federal Reserve Bank to have access to confidential supervisory information with respect to a SIDCO. The Commission recognized, however, that the fact that Board supervisory staff may have access to confidential supervisory information about a SIDCO could create the false perception that Federal Reserve Bank staff responsible for managing the SIDCO's account and financial services would gain special knowledge about the SIDCO. As a result, the Commission recognized that a Federal Reserve Bank acting as a depository for customer funds could face greater scrutiny than a commercial bank acting as such. Therefore, the proposed order included a statement recognizing that, pursuant to the Wall Policy,[18] information obtained by the Board supervisory staff during the course of supervising SIDCOs or any counterparty to a SIDCO will not be attributed by the Commission to any Federal Reserve Bank providing accounts and financial services to SIDCO account holders.

III. Public Comments

In response to its request for public comment on the Proposal, the Commission received six comment letters.[19] All six letters expressly supported the issuance of an order exempting the Federal Reserve Banks from Sections 4d and 22 of the CEA, citing such benefits as mitigating systemic risk in the clearing and settlement system, reducing credit and liquidity risks for Designated FMUs, and enhancing the protection of customer funds.

Specifically, ICC agreed that holding SIDCO customer funds at a Federal Reserve Bank would decrease the SIDCO's credit, liquidity, and operational risks. ICC also agreed that ''the existing limitations on how Federal Reserve Banks hold assets provide adequate protections to account holders,'' and ''such protections are consistent with the customer protection initiatives of the CEA.''[20] ICC and the International Swaps and Derivatives Association, Inc. (''ISDA'') both noted that the use of a Federal Reserve Bank as a depository for SIDCO customer funds would help to reduce systemic risk by reducing interconnectedness in the financial system. ISDA observed that such interconnectedness is particularly present when one firm simultaneously acts as a custodial bank, settlement bank, and/or clearing member with

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held in accordance with Section 4d of the CEA to ensure that the depository has been informed that the deposited funds are those of customers.

[14] *See id.* at 35340–35342.

[15] The operating circulars of the Federal Reserve Banks began having uniform terms and conditions across Federal Reserve Bank districts as of January 2, 1998.

[16] In fact, SIDCOs have established proprietary accounts with one or more Federal Reserve Banks that are governed by the Federal Reserve Bank Governing Documents.

[17] In the Proposal, the Commission explained that Section 22 of the CEA provides for private rights of action for damages against persons who violate the CEA, or persons who willfully aid, abet, counsel, induce, or procure the commission of a violation of the CEA. *See* 81 FR at 35342; *see also* 7 U.S.C. 25. The Commission noted that under the Federal Reserve Bank Governing Documents, the Federal Reserve Banks are currently insulated from third-party claims. While the Commission continues to believe that private claims empower injured parties to seek compensation for damages where the Commission lacks the resources to do so on their behalf, and the prospect of such claims serves the public interest in deterring misconduct, the Commission has determined that, for the reasons discussed herein and in the Proposal, exempting the Federal Reserve Banks from liability under Section 22 of the CEA would also serve the public interest.

[18] As discussed in greater detail in the Proposal, Board staff has represented that it has a long-standing ''Wall Policy'' that generally prohibits, subject to the limitations contained therein, the sharing of confidential supervisory information with Federal Reserve Bank account services staff, and requires that care be exercised to avoid actual or apparent conflict between a Federal Reserve Bank's role as a provider of financial services and its role as a regulator, supervisor, and lender. *See* 81 FR at 35341; *see also* Federal Reserve's Key Policies for the Provision of Financial Services: Standards Related to Priced-Service Activities of the Federal Reserve Banks (1984), *available at http://www.federalreserve.gov/paymentsystems/pfs_standards.htm.*

[19] Letters were submitted by CME, ICC, and OCC (each of which is a Designated FMU), Minneapolis Grain Exchange, Inc. (which is a DCO), American Council of Life Insurers, and the International Swaps and Derivatives Association, Inc. The Commission also received one non-substantive comment. All comments referred to herein are available on the Commission's Web site, at *http://comments.cftc.gov/PublicComments/CommentList.aspx?id=1703.*

[20] ICC Comment Letter at 2 (July 1, 2016).

respect to one central counterparty.[21] ISDA believes that reducing this interconnectedness would positively impact SIDCO resilience during a market disruption and promote safety and soundness in the cleared derivatives markets by decreasing contagion risk. Furthermore, in ISDA's view, customer accounts at Federal Reserve Banks would only benefit derivatives customers and promote safety and soundness in the cleared derivatives markets. ISDA believes that the strict limitations on how the Federal Reserve Banks hold deposits adequately protect customers without the additional safeguards provided under Sections 4d and 22 of the CEA.

The Commission requested comments regarding whether the proposed exemption should be expanded to include not just SIDCOs but all Designated FMUs (in other words, all registered DCOs that have been designated as systemically important by the Council, regardless of whether the Commission is the DCO's Supervisory Agency). In response, OCC requested that the Commission expand the exemption.[22] As previously noted, OCC is currently designated by the Council to be systemically important; however, it is not a SIDCO, as the Securities and Exchange Commission is its Supervisory Agency. OCC commented that Section 806(a) of the Dodd-Frank Act supports Federal Reserve Banks acting as depositories for all Designated FMUs and not just SIDCOs. OCC argued that denying it the opportunity to deposit segregated customer funds in a Federal Reserve Bank account would undermine one of the purposes of Title VIII and would place OCC at an unjustified competitive disadvantage with respect to other Designated FMUs. ISDA also urged the Commission to expand the exemption to include customer accounts at a Federal Reserve Bank established by Designated FMUs given the benefits associated with holding customer accounts with a Federal Reserve Bank.

Minneapolis Grain Exchange, Inc. (''MGEX'') requested that the Commission expand the exemption to include customer accounts held at Federal Reserve Banks by Subpart C DCOs.[23] MGEX stated that limiting access to Federal Reserve Bank services and accounts to SIDCOs creates a competitive disadvantage to those DCOs that have not been designated as systemically important because such DCOs would not have access to these credit and liquidity risk reducing opportunities afforded to SIDCOs.[24] MGEX commented that this disadvantage may be more pronounced for Subpart C DCOs because they are held to the same standards as SIDCOs but do not have access to accounts at the Federal Reserve Banks.[25] MGEX recognized, however, that this is due to the ''restrictive wording'' of Section 806(a) of the Dodd-Frank Act, which specifically limits access to Federal Reserve Bank accounts to Designated FMUs, and the Commission cannot simply grant Subpart C DCOs permission to have accounts at a Federal Reserve Bank.[26] MGEX requested that the Commission use alternative language in the exemptive order, so as not to be SIDCO-specific, in the event that Federal Reserve Banks are subsequently permitted to maintain accounts for Subpart C DCOs in the future.

CME supported the exemption, but noted that it would be inconsistent with Commission Regulation 1.20(g)(4)(ii), which requires that a DCO obtain from a Federal Reserve Bank acting as a depository for customer funds a written acknowledgment that the customer funds are being held in accordance with Section 4d of the CEA.[27] CME noted, however, that pursuant to the terms of the exemptive order, the Federal Reserve Banks would be exempt from Section 4d.[28] CME suggested that the exemptive order and Commission Regulation 1.20(g)(4)(ii) be harmonized.

In addition, CME commented that, as a SIDCO account holder, it would need multiple Federal Reserve Bank accounts in order to comply with the segregation requirements set forth in the exemptive order.[29] CME stated that, under the Federal Reserve Banks' Operating Circular 1, a financial institution may maintain only one Master Account with a Federal Reserve Bank, although the Federal Reserve Bank may, in its discretion, allow multiple Master Accounts in certain situations. CME noted that this may require a Federal Reserve Bank to exercise its discretion under its standard policies and operating circulars to permit the use of multiple Master Accounts for SIDCO account holders.

CME also stated that account agreements between the Federal Reserve Banks and depository institution account holders typically include certain set-off rights and liens in favor of the Federal Reserve Banks. In this regard, CME commented that Federal Reserve Bank account agreements may need to be tailored in order to provide comfort to SIDCO clearing members, and customers of SIDCO clearing members, that their margin deposits are ''bankruptcy remote'' from the SIDCO under applicable bank capital requirements.[30] Similarly, American Council of Life Insurers (''ACLI'') requested that the Commission clarify ''for the benefit of public customers who are the ultimate beneficiaries of segregated accounts at commercial or federal banks, that customer segregated funds (*i.e.,* initial margin) shall never be used for any other purpose under any circumstances, even the most exigent.'' [31]

IV. Findings and Conclusions

After careful review and consideration of the comments, and for the reasons cited herein and set forth in the Proposal, the Commission has determined that the requirements of Section 4(c) of the CEA have been met with respect to exempting Federal Reserve Banks that provide customer accounts and other services to Designated FMUs from Sections 4d and 22 of the CEA. The Commission is therefore issuing an order granting the exemption essentially as proposed. However, the Commission is making minor technical clarifications to the language of the order, and is expanding the exemption to include those customer accounts that are established pursuant to the CEA and that are held at Federal Reserve Banks by Designated FMUs. The Commission agrees with OCC and ISDA that Section 806(a) of the Dodd-Frank Act supports Federal

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[21] ISDA Comment Letter at 2 (July 5, 2016).

[22] OCC Comment Letter at 1 (July 5, 2016).

[23] A Subpart C DCO is a DCO registered with the Commission pursuant to Section 5b of the CEA that is not a SIDCO and has elected to become subject to the requirements of Subpart C of Part 39 of the Commission's regulations. 17 CFR 39.2. MGEX has made this election and is therefore a Subpart C DCO.

[24] MGEX Comment Letter at 1 (July 5, 2016).

[25] SIDCOs and Subpart C DCOs are required to comply with the requirements set forth in Subpart C of Part 39 of the Commission's regulations, as well as the requirements applicable to all DCOs, which are set forth in Subparts A and B of Part 39. Subpart C, together with the provisions in Subparts A and B, establish domestic regulations that are consistent with the Principles for Financial Market Infrastructures. As a result, SIDCOs and Subpart C DCOs are considered qualified central counterparties for purposes of the Basel capital requirements for central counterparties. *See, e.g.,* Derivatives Clearing Organizations and International Standards, 78 FR 72476 (Dec. 2, 2013) (discussing the regulatory framework for SIDCOs and Subpart C DCOs and providing further background on qualified central counterparties).

[26] MGEX Comment Letter at 2 (July 5, 2016).

[27] 17 CFR 1.20(g)(4)(ii).

[28] CME Comment Letter at 3 (July 1, 2016).

[29] As a condition to the exemptive order, the Federal Reserve Banks are required to segregate customer funds deposited by a Designated FMU from the proprietary funds deposited by a Designated FMU.

[30] CME Comment Letter at 4 (July 1, 2016).

[31] ACLI Comment Letter at 2 (July 5, 2016).

Reserve Banks acting as depositories for all Designated FMUs, not just SIDCOs.

The Commission notes MGEX's request that the Commission expand the exemption to include customer accounts held at Federal Reserve Banks by any Subpart C DCO. However, the Commission further notes that Subpart C DCOs are not currently eligible for Federal Reserve Bank accounts.[32] Accordingly, the Commission is declining to expand the exemption to include customer accounts held at Federal Reserve Banks by Subpart C DCOs. As MGEX acknowledges, the Commission does not have the authority to direct the Federal Reserve Banks to provide accounts and services to Subpart C DCOs. If, in the future, a registered DCO that is not a Designated FMU is able to establish an account at a Federal Reserve Bank, the Commission may reconsider the scope of the exemption at that time.

In response to CME's comment that the exemption would be inconsistent with the acknowledgement letter requirements in Commission Regulation 1.20(g)(4)(ii),[33] the Commission agrees and has determined to repeal this requirement[34] in a separate **Federal Register** notice. The exemptive order will render these provisions inapplicable, as the Federal Reserve Banks that provide customer accounts and other services to Designated FMUs would be exempt from Section 4d of the CEA.

In addition, CME commented that, as a SIDCO account holder, it would need multiple Federal Reserve Bank accounts in order to comply with the segregation requirements set forth in the exemptive order.[35] CME noted that obtaining multiple Master Accounts may require a Federal Reserve Bank to exercise its discretion under its standard policies and operating circulars. The Commission agrees that this issue would appear to be within the scope of the Federal Reserve's authority and not the Commission's.

CME also noted that account agreements between the Federal Reserve Banks and depository institution account holders typically include certain set-off rights and liens in favor of the Federal Reserve Banks. CME argued that Federal Reserve Bank account agreements may need to be revised to make sure customer margin deposits are "bankruptcy remote" from the SIDCO under applicable bank capital requirements.[36] Similarly, ACLI argued that the interests of customers in their segregated funds should never be subordinated for the benefit of any other party. The Commission agrees that a Designated FMU cannot grant security interests in, rights of set-off against, or other rights in customer collateral. Therefore, the Commission believes that a Designated FMU's account agreement must be free from any rights of set-off or liens on customer funds.

The exemptive order applies to all Federal Reserve Banks that provide customer accounts and other services to Designated FMUs. It requires that all money, securities, and property deposited into a customer account established pursuant to the CEA by a Designated FMU with a Federal Reserve Bank must be separately accounted for and not commingled with the money, securities, and property deposited into the account of any other person, including a proprietary account of the Designated FMU depositing such funds.[37] In addition, Federal Reserve Banks must reply promptly and directly to any request for confirmation of account balances or provision of any other information regarding or related to the customer account(s) of a Designated FMU that are established pursuant to the CEA from the director of the Division of Clearing and Risk of the Commission, or any successor division, or such director's designees.

In light of the foregoing, the Commission believes the exemption would promote responsible economic and financial innovation and fair competition, and is consistent with the "public interest," as that term is used in Section 4(c) of the CEA.

V. Related Matters

A. Regulatory Flexibility Act

The Regulatory Flexibility Act ("RFA")[38] requires federal agencies, in promulgating rules, to consider whether those rules will have a significant economic impact on a substantial number of small entities and, if so, provide a regulatory flexibility analysis respecting the impact. The Commission believes that the exemptive order will not have a significant economic impact on a substantial number of small entities. The exemption will impact Designated FMUs and Federal Reserve Banks. The Commission has previously established certain definitions of "small entities" to be used by the Commission in evaluating the impact of its actions on small entities in accordance with the RFA.[39] The Commission has previously determined that DCOs, including Designated FMUs, are not small entities for purposes of the RFA.[40] Similarly, the Commission believes that Federal Reserve Banks are not small entities for purposes of the RFA.

Accordingly, the Commission does not expect the exemption to have a significant impact on a substantial number of small entities. Therefore, the Chairman, on behalf of the Commission, hereby certifies, pursuant to 5 U.S.C. 605(b), that the exemption would not have a significant economic impact on a substantial number of small entities.

B. Paperwork Reduction Act

The purposes of the Paperwork Reduction Act of 1995 ("PRA")[41] are, among other things, to minimize the paperwork burden to the private sector, ensure that any collection of information by a government agency is put to the greatest possible uses, and minimize duplicative information collections across the government. The PRA applies to all information, regardless of form or format, whenever the government is obtaining, causing to be obtained or soliciting information, and requires disclosure to third parties or the public, of facts or opinions, when the information collection calls for answers to identical questions posed to, or identical reporting or recordkeeping requirements imposed on, ten or more persons. The PRA would not apply in this case given that the exemption would not impose any new recordkeeping or information collection requirements, or other collections of information on ten or more persons that require approval of the Office of Management and Budget.

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[32] Federal Reserve Banks serve only account holders authorized by statute, such as depository institutions and the U.S. government. *See, e.g.,* Federal Reserve Bank of Richmond, Consumer Issues and Information, *available at https://www.richmondfed.org/faqs/consumer/* (last visited Feb. 26, 2016) (stating that "Federal Reserve Banks are not authorized to open accounts for individuals[; rather, o]nly depository institutions and certain other financial entities may open an account at a Federal Reserve Bank"); *see also* Section 806(a) of the Dodd-Frank Act (authorizing accounts at a Federal Reserve Bank for designated FMUs).

[33] 17 CFR 1.20(g)(4)(ii). Under Commission Regulation 1.20(g)(4)(ii), a DCO must obtain from a Federal Reserve Bank acting as a depository for customer funds a written acknowledgement that (A) The Federal Reserve Bank was informed that the customer funds deposited therein are those of customers and are being held in accordance with the provisions of section 4d of the CEA and Commission regulations thereunder; and (B) The Federal Reserve Bank agrees to reply promptly and directly to any request from Commission staff for confirmation of account balances or provision of any other information regarding or related to an account. *Id.*

[34] Specifically, the Commission is revising paragraphs (g)(4)(i) and (g)(4)(ii), and repealing paragraphs (g)(4)(ii)(A) and (g)(4)(ii)(B).

[35] As a condition to the exemptive order, the Federal Reserve Banks are required to segregate customer funds deposited by a Designated FMU from the proprietary funds deposited by a Designated FMU.

[36] CME Comment Letter at 4 (July 1, 2016).

[37] The Commission is slightly modifying the language from the proposed order so that the exemptive order makes clear that customer funds deposited by a Designated FMU may not be commingled with funds held in any other account at the Federal Reserve Banks, including the Designated FMU's proprietary account. This language is included in the order because, despite the exemption for the Federal Reserve Banks, a Designated FMU is still subject to the requirements of Section 4d of the CEA and Commission Regulation 1.20, which require a DCO to separately account for and segregate customer funds. Specifically, the Commission is changing the phrase "separately accounted for and segregated from" in the proposed order to "separately accounted for and not commingled with" to more closely mirror the language used in Section 4d. For purposes of this exemption, customer funds held by the Federal Reserve Banks can meet this standard so long as the customer funds are held in a separate account and the funds in the customer account are not used to pay or secure the obligations arising out of any other account.

[38] 5 U.S.C. 601 *et seq.*

[39] *See* 47 FR 18618, 18618–21 (Apr. 30, 1982).

[40] *See* New Regulatory Framework for Clearing Organizations, 66 FR 45604, 45609 (Aug. 29, 2001).

[41] 44 U.S.C. 3501 *et seq.*

C. Cost and Benefit Considerations

1. Summary of Comments on the Costs and Benefits of the Proposed Order

The Commission requested comments on the costs and benefits associated with the proposed order. The Commission requested but received no comments providing data or other information to enable the Commission to better quantify the expected costs and benefits attributable to this exemption. In terms of qualitative cost and benefit comments, OCC stated that Section 806(a) of the Dodd-Frank Act supports Federal Reserve Banks acting as depositories for all Designated FMUs and not just SIDCOs. OCC commented that limiting the exemption to SIDCO customer accounts would place OCC at a competitive disadvantage because, although OCC is a Designated FMU, it is not a SIDCO. In addition, OCC argued that denying OCC the opportunity to deposit customer funds at a Federal Reserve Bank would undermine the purpose of Title VIII of the Dodd-Frank Act.

MGEX also supported the proposed exemption, but noted that DCOs that are not designated as systemically important would not have the same access to the credit and liquidity risk reducing opportunities afforded to SIDCOs with access to Federal Reserve Bank accounts. MGEX stated that limiting access to Federal Reserve Bank accounts to SIDCOs would create a competitive disadvantage to those DCOs that are not designated as systemically important, particularly Subpart C DCOs. MGEX recognized that the Commission cannot grant Subpart C DCOs permission to have accounts at a Federal Reserve Bank. However, MGEX argued that the Commission should expand the exemption to cover customer accounts maintained by Federal Reserve Banks for Subpart C DCOs in the event that Federal Reserve Banks are subsequently permitted to maintain accounts for Subpart C DCOs.

ICC commented that accounts at Federal Reserve Banks would reduce credit, operational, and liquidity risks that are associated with traditional deposit accounts. ISDA and ICC further noted that such accounts may reduce interconnectedness in the cleared derivatives market. CME commented that migrating a portion of the eligible assets it has on deposit from clearing members to a Federal Reserve Bank may have a number of positive effects on its clearing members and their customers. ACLI stated that the proposed order would reduce overall systemic risk that could arise from liquidity and other risks on commercial banks where SIDCOs currently deposit their customer funds.

In the discussion that follows, the Commission considers the costs and benefits of the exemptive order to the public and market participants. It also considers the costs and benefits of the exemption in light of the public interest factors enumerated in Section 15(a) of the CEA.

2. Costs

This order is exemptive and provides the Federal Reserve Banks relief from certain of the requirements in the CEA and attendant Commission regulations. As with any exemptive rule or order, the exemption in the order is permissive, meaning that the Federal Reserve Banks are not required to rely on it. In addition, Designated FMUs are not required to deposit customer funds with a Federal Reserve Bank. Accordingly, the Commission assumes that interested parties would rely on the exemption only if the anticipated benefits warrant the costs of the exemption.

The exemptive order would exempt the Federal Reserve Banks from Sections 4d and 22 of the CEA. All of the commenters generally supported issuing this exemption. However, two commenters raised the possibility that the proposed order could place them at a competitive disadvantage. First, as discussed above, OCC argued that, under Title VIII of the Dodd-Frank Act, a Federal Reserve Bank may be permitted to maintain an account for a Designated FMU. OCC argued that, as a result, it would be placed at a competitive disadvantage with respect to SIDCOs. The Commission agrees that Title VIII of the Dodd-Frank Act permits Federal Reserve Banks to maintain accounts for, and provide services to, Designated FMUs, and not just SIDCOs. Accordingly, and as discussed above, the Commission has determined to expand the exemption to include customer accounts held at Federal Reserve Banks by Designated FMUs generally, for purposes of consistency with Title VIII.

Second, MGEX argued that it would be placed at a competitive disadvantage with respect to SIDCOs because, as a Subpart C DCO, MGEX is held to the same standards as SIDCOs under the Commission's regulations, but is not afforded the same opportunity to hold customer accounts at a Federal Reserve Bank. The Commission has declined to expand the exemption to include customer accounts held at Federal Reserve Banks by Subpart C DCOs. Under Title VIII, the Board may authorize a Federal Reserve Bank to maintain accounts only for Designated FMUs. As MGEX recognizes, the Commission does not have the authority to authorize a Federal Reserve Bank to maintain accounts for Subpart C DCOs. Accordingly, the competitive disadvantage identified by MGEX cannot be remedied by the Commission by expanding the scope of the exemption. Moreover, the Commission does not believe it would be appropriate to expand the scope of the exemption based on the theoretical possibility that Federal Reserve Banks may one day be permitted to provide accounts to Subpart C DCOs. In the event that a Federal Reserve Bank is authorized to maintain an account for other registered DCOs, the Commission may reconsider the scope of the exemptive relief at that time.

3. Benefits

The exemption will benefit market participants by facilitating Designated FMUs' use of Federal Reserve Banks as depositories for customer funds. Whereas commercial banks present credit and liquidity risks to a Designated FMU, its FCM clearing members, and the FCMs' customers, the Federal Reserve Banks are substantially insulated from such risks. As discussed in greater detail above, Title VIII of the Dodd-Frank Act was enacted to mitigate systemic risk in the financial system and to promote financial stability, in part, through an enhanced supervisory framework for Designated FMUs. In addition to this framework, Title VIII, and more specifically, Section 806(a) of the Dodd-Frank Act, permits the Board to authorize a Federal Reserve Bank to establish and maintain an account for a

Designated FMU and provide to the Designated FMU certain financial services. By enacting Title VIII in general, and Section 806(a) in particular, Congress recognized the importance of reducing systemic risk and providing Designated FMUs with a potential safeguard during an extraordinary liquidity event. The exemption would therefore help promote Congress' goal of better preparing the U.S. financial system for potential future liquidity events.[42] Commenters generally agreed that the exemption would benefit market participants by enhancing the protection of customer funds. Commenters noted that accounts at Federal Reserve Banks would decrease a SIDCO's credit, liquidity and operational risk, and reduce interconnectedness in the cleared derivatives market.

Moreover, the Federal Reserve Banks' standard of liability, as set forth in the Federal Reserve Bank Governing Documents, is better suited for the Federal Reserve Banks than Section 4d of the CEA, which was designed to govern customer funds deposited with a commercial bank, trust company, or DCO. Unlike commercial banks, Federal Reserve Banks do not operate for profit and serve only account holders authorized by statute, such as depository institutions and the U.S. government. Indeed, each year they return to the U.S. Department of Treasury all earnings in excess of Federal Reserve Bank operating and other expenses, such as litigation expenses. By exempting the Federal Reserve Banks from certain potential enforcement actions and private suits, the exemption would reduce the Federal Reserve Banks' exposure to litigation. Because the Federal Reserve Banks return their earnings to the U.S. Department of Treasury's general fund, U.S. taxpayers could benefit from the exemption. Therefore, the Commission believes that it is appropriate to apply the Federal Reserve Banks' standard of liability in order to facilitate the use of these accounts.

4. Section 15(a) Factors

Section 15(a) of the CEA requires the Commission to consider the costs and benefits of its action before issuing an order under the CEA.[43] By its terms, Section 15(a) does not require the Commission to quantify the costs and benefits of an order or to determine whether the benefits of the order outweigh its costs. Rather, Section 15(a) simply requires the Commission to "consider the costs and benefits" of its action.

Section 15(a) of the CEA further specifies that costs and benefits shall be evaluated in light of five broad areas of market and public concern: (1) Protection of market participants and the public; (2) efficiency, competitiveness, and financial integrity of futures markets; (3) price discovery; (4) sound risk management practices; and (5) other public interest considerations. The Commission may in its discretion give greater weight to any one of the five enumerated areas and could in its discretion determine that, notwithstanding its costs, a particular order is necessary or appropriate to protect the public interest or to effectuate any of the provisions or to accomplish any of the purposes of the CEA.

a. Protection of Market Participants and the Public

The exemption would serve to facilitate Designated FMUs' use of Federal Reserve Banks as depositories for customer funds. Because the Federal Reserve System is the nation's central bank, such accounts would provide Designated FMUs with the lowest possible credit risk in the event of a market disruption. Moreover, as Federal Reserve Banks are the source of liquidity with regard to U.S. dollar deposits, Designated FMUs with access to a deposit account at a Federal Reserve Bank would also be better equipped to handle a liquidity event. Since Designated FMUs have been so designated because of their importance to the broader financial system, reducing these risks would protect market participants and the public.

b. Efficiency, Competitiveness, and Financial Integrity

A temporary or permanent disruption to the operations of a Designated FMU could cause widespread and significant damage to the financial integrity of derivatives markets as a whole. Therefore, by facilitating a Designated FMU's use of Federal Reserve Banks as depositories for customer funds, the exemption would reduce liquidity and credit risk to the Designated FMU, which would, in turn, promote the financial integrity of the derivatives markets.

As noted above, two commenters raised concerns that the exemptive order may result in a competitive disadvantage. The Commission has addressed the concern of one commenter (OCC) by expanding the exemption to include customer accounts held at Federal Reserve Banks by Designated FMUs generally. On the other hand, the Commission does not have the authority to take action to address the concerns of the other commenter (MGEX).

The Commission does not anticipate the exemption will have a significant impact on the efficiency of the derivatives markets.

c. Price Discovery

The Commission does not anticipate the exemption will have an impact on the price discovery process.

d. Sound Risk Management Practices

The Commission believes that establishing segregated customer accounts for Designated FMUs and enabling Designated FMUs to access related services at a Federal Reserve Bank would improve a Designated FMU's ability to manage liquidity risk and protect customer funds. Additionally, the Commission believes that the availability of a Federal Reserve Bank account could allow a Designated FMU to reduce its concentration risk by adding an additional creditworthy depository in which to diversify funds. Accordingly, the exemption promotes sound risk management practices.

The Commission further notes that, notwithstanding the exemption from Section 4d of the CEA, the Federal Reserve Banks are still required to segregate customer funds deposited by a Designated FMU from the proprietary funds deposited by a Designated FMU and to adhere to the longstanding standards of liability that govern the Federal Reserve Banks.

e. Other Public Interest Considerations

The Commission believes that facilitating a Designated FMU's access to Federal Reserve Bank accounts will promote the public interest by bolstering a Designated FMU's ability to conduct settlements with a high degree of confidence under a wide range of stress scenarios, thereby increasing the likelihood of the Designated FMU being able to provide its customers with access to their funds in times of market distress.

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[42] A Designated FMU's access to Federal Reserve Bank deposit accounts is also consistent with the international standards set forth in the Principles for Financial Market Infrastructures, which acknowledge the protections afforded by central banks from such credit and liquidity risks. *See, e.g.*, CPSS–IOSCO, Principles for Financial Market Infrastructures, ¶ 3.9.3 (noting that "[c]entral banks have the lowest credit risk and are the source of liquidity with regard to their currency of issue"); *see also* Principles for Financial Market Infrastructures, Key Consideration 8 (specifying that a financial market infrastructure "with access to central bank accounts, payment services, or securities services should use these services, where practical, to enhance its management of liquidity risk").

[43] 7 U.S.C. 19(a).

VI. Order of Exemption

After considering the above factors and the comment letters received in response to the request for comments, the Commission has determined to issue the following:

Order

Pursuant to Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act ("Dodd-Frank Act"), the Financial Stability Oversight Council ("Council") is required to designate those financial market utilities ("FMUs") that the Council determines are, or are likely to become, systemically important. A derivatives clearing organization registered with the Commodity Futures Trading Commission ("Commission") and designated by the Council as systemically important is referred to herein as a "Designated FMU". Under Section 806(a) of the Dodd-Frank Act, the Board of Governors ("Board") of the Federal Reserve System is permitted to authorize a Federal Reserve Bank to establish and maintain a deposit account for, among others, a Designated FMU and provide certain services to the Designated FMU, subject to any applicable rules, orders, standards, or guidelines prescribed by the Board.

Designated FMUs are required to hold funds belonging to customers of their clearing members in accounts subject to Section 4d of the Commodity Exchange Act ("CEA"). In addition, Section 22 of the CEA would provide for private rights of action for damages against persons who violate Section 4d, or persons who willfully aid, abet, counsel, induce, or procure the commission of a violation of Section 4d. However, the Commission understands that deposit accounts maintained by any Federal Reserve Bank would be governed by applicable account agreements, operating circulars issued by Federal Reserve Banks for each service, the Federal Reserve Act, and Federal Reserve regulations and policies, and, with respect to book-entry securities services, the regulations of the domestic issuer of the securities or the issuer's regulator ("Federal Reserve Bank Governing Documents"). The Federal Reserve Bank Governing Documents, as may be amended from time to time, include, but are not limited to, Federal Reserve Bank Operating Circular No. 6 (governing funds transfers through the Fedwire Funds Service); Federal Reserve Bank Operating Circular No. 7 (governing the maintenance of and transfer services for book-entry securities accounts); 12 CFR part 210, subpart B (governing funds transfers through the Fedwire Funds Service); and 31 CFR part 357, subpart B (setting forth the U.S. Department of the Treasury's regulations governing book-entry treasury bonds, notes, and bills).

The Commission understands that under the Federal Reserve Bank Governing Documents, a Federal Reserve Bank has no requirement or obligation to inquire as to the legitimacy or accuracy of the instructions, or the transactions related to those instructions, or compliance by the Designated FMU with its obligations under the CEA. To the extent that liability may accrue under the Federal Reserve Bank Governing Documents, the Commission understands that the Federal Reserve Bank may be held liable only for actual damages that are (i) incurred solely by the Designated FMU account holder, and (ii) proximately caused by the Federal Reserve Bank's failure to exercise ordinary care or act in good faith in accordance with the Federal Reserve Bank Governing Documents. The Commission is issuing an exemption to the Federal Reserve Banks in order to facilitate Federal Reserve Banks' ability to establish customer accounts for Designated FMUs.

Therefore, *it is ordered,* pursuant to Section 4(c) of the CEA, 7 U.S.C. 6(c), that the Federal Reserve Banks are granted an exemption from Sections 4d and 22 of the CEA, subject to the terms and conditions specified herein:

1. Segregation. Money, securities, and property deposited into a customer account established pursuant to the CEA by a Designated FMU with a Federal Reserve Bank shall be separately accounted for and not commingled with the money, securities, and property deposited into the account of any other person, including a proprietary account of the Designated FMU depositing such funds.

2. Information Requests. Federal Reserve Banks must reply promptly and directly to any request for confirmation of account balances or provision of any other information regarding or related to the customer account(s) of a Designated FMU that are established pursuant to the CEA from the director of the Division of Clearing and Risk of the Commission, or any successor division, or such director's designees.

3. Applicability to Federal Reserve Banks. Subject to the conditions contained herein, the order applies to all Federal Reserve Banks that provide customer accounts and other services to Designated FMUs. In addition, pursuant to the Federal Reserve's Key Policies for the Provision of Financial Services: Standards Related to Priced-Service Activities of the Federal Reserve Banks, information obtained by the Board of Governors of the Federal Reserve System or its designees during the course of supervising Designated FMUs, pursuant to Title VIII of the Dodd-Frank Act, or any counterparty to a Designated FMU under any authority, shall not be attributed by the Commission to any Federal Reserve Bank providing accounts and financial services to Designated FMU account holders.

4. Reservation of Rights. This order is based upon the analysis set forth above. Any material change in law or circumstances pursuant to which this order is granted might require the Commission to reconsider its finding that the exemption contained herein is appropriate and/or consistent with the public interest and purposes of the CEA. Further, the Commission reserves the right, in its discretion, to revisit any of the terms and conditions of the relief provided herein, including but not limited to, making a determination that certain entities described herein should be subject to the Commission's full jurisdiction, and to condition, suspend, terminate, or otherwise modify or restrict the exemption granted in this order, as appropriate, upon its own motion.

Issued in Washington, DC, on August 8, 2016, by the Commission.

Christopher J. Kirkpatrick,
Secretary of the Commission.

Appendices to Order Exempting the Federal Reserve Banks From Sections 4d and 22 of the Commodity Exchange Act—Commission Voting Summary, Chairman's Statement, and Commissioner's Statement

Appendix 1—Commission Voting Summary

On this matter, Chairman Massad and Commissioners Bowen and Giancarlo voted in the affirmative. No Commissioner voted in the negative.

Appendix 2—Statement of Chairman Timothy G. Massad

Today, the Commission continues its work to ensure the resiliency of clearinghouses and protect customers in our markets. To provide the necessary context for these efforts, it is useful to look back at recent history.

Most participants in our markets will recall what happened at the beginning of the financial crisis in September 2008, when the Reserve Fund—a money market fund—"broke the buck" following the bankruptcy of Lehman Brothers. Redemptions were suspended and investors were not able to make withdrawals. As a result, many futures commission merchants (FCMs) were not able to access customer funds invested in the Reserve Fund. Absent relief by the CFTC, many would have been undercapitalized, potentially ending up in bankruptcy. In addition, clearinghouses could not liquidate investments in the Reserve Fund. And there could have easily been a widespread run on money market funds, but for the emergency actions taken by the U.S. government.

As a result of the crisis, as well as the collapse of MF Global, the CFTC and our self-regulatory organizations took a number of actions to better protect customer funds. We required customer funds to be strictly segregated and limited the ways they can be invested. We enhanced accounting and auditing procedures at FCMs, including by requiring daily verification from depositories of the amounts deposited by FCMs.

Today, CFTC rules require that customer funds be invested in highly liquid assets and be convertible into cash within one business day without a material discount in value. Our rules also require that clearinghouses invest initial margin deposits in a manner that allows them to promptly liquidate any such investment.

Over the last few years, the Securities and Exchange Commission (SEC) has also taken action in response to the lessons of the financial crisis, by adopting a number of measures to address the potential vulnerabilities of money market funds. One such recent reform, which takes effect in October of this year, sets forth the circumstances where prime money market funds are permitted, or in some circumstances required, to suspend redemptions in order to prevent the risk of investor runs.

While we recognize the benefit of the SEC's new rule in preventing investor runs, a suspension of redemptions by a money market fund would mean investments in such funds are not accessible and cannot be promptly liquidated. Such an event could result in customers, FCMs, and clearinghouses being unable to access the funds necessary to satisfy margin obligations.

Therefore, CFTC staff is today providing guidance making clear that Commission rules prohibit a clearing member from investing customer funds, or a clearinghouse from investing amounts deposited as initial margin, in such money market funds.

Some industry participants have suggested we should interpret or revise our rules to permit investments of at least some customer monies in such money market funds unless and until redemptions are suspended. We have declined to do so, as it would be too late to protect customers at that point. Moreover, there are alternatives to prime funds, including certain government money markets funds or Treasury securities. In fact, investments in prime money market funds represent a relatively small portion of the total customer funds on deposit and the total initial margin deposits at clearinghouses. Some of our clearinghouses and FCMs do not have any investments in prime funds.

Staff has been careful not to be overly restrictive, and therefore has issued no-action relief to allow FCMs to invest certain "excess" proprietary funds held in customer accounts in these money market funds. That is, our existing rules require FCMs to deposit their own funds (*i.e.,* targeted residual interest) into customer accounts to make sure that there are sufficient funds in the segregated customer accounts to cover all obligations due to customers. FCMs frequently deposit an amount of their own funds that is in excess of the targeted residual interest amount required under our rules, and that excess amount can be withdrawn at any time. Indeed, if an FCM should default, customers—and the system as a whole—are better off if excess funds are on deposit, and we do not wish to incentivize FCMs to withdraw such excess funds from the segregated account. Therefore, the no action relief makes clear that FCMs can continue to invest their own funds in excess of their targeted residual interest in such money market funds, even though they cannot invest the customer funds—or any proprietary funds they are required to deposit—in this manner.

Finally, the Commission is taking action today that will further ensure the safety of customer funds. We are issuing an order that will help make it possible for systemically important clearinghouses to deposit customer funds at Federal Reserve Banks. Our order makes clear that a Federal Reserve Bank that opens such an account would be subject to the same standards of liability that generally apply to it as a depository, rather than any potentially conflicting standard under the commodity laws.

Although Federal Reserve accounts for customer funds held by systemically important clearinghouses do not exist today, they are allowed under the Dodd-Frank Act, and we have been working with the Board of Governors to facilitate them. The two clearinghouses designated as systemically important in our markets have been approved to open Federal Reserve Bank accounts for their proprietary funds. We hope that with today's action, accounts for customer funds can be opened soon. Doing so will help protect customer funds and enhance the resiliency of clearinghouses.

I thank the dedicated CFTC staff and my fellow Commissioners for their work on these matters.

Appendix 3—Concurring Statement of Commissioner Sharon Y. Bowen

I am pleased to concur with the two Commission actions: The "Order Exempting the Federal Reserve Banks from Sections 4d and 22 of the Commodity Exchange Act" and "Written Acknowledgment of Customer Funds from Federal Reserve Banks." I have long believed that, in order to protect customer funds, we need to keep that money at our central bank. In the event of a major market event, I, and I believe the rest of the American people, would feel much better knowing that investors' money is at the Federal Reserve instead of at multiple central counterparties. I am glad that our agency and the Federal Reserve have come to an agreement on an effective way to accomplish this.

I am similarly pleased with the Division of Clearing and Risk's (DCR) "Staff Interpretation Regarding CFTC Part 39 In Light Of Revised SEC Rule 2a–7," which clearly outlines the staff's understanding that, given the limitations that the Securities and Exchange Commission (SEC) has imposed on redemptions for prime money market funds, that they are no longer considered Rule 1.25 assets. This is the correct interpretation. The key feature in a Rule 1.25 asset is that it must be available quickly in times of crisis or illiquidity. And we know that funds are more likely to close the gates on redemptions when market dislocation happens. That is just the time when futures commission merchants (FCMs) and customers would need access to their money, and a multi-day delay can mean catastrophe for some businesses.

For that very reason, I have concerns about the Division of Swap Dealer and Intermediary Oversight's (DSIO) "No-Action Relief With Respect to CFTC Regulation 1.25 Regarding Money Market Funds." While the 4(c) exemption and the DCR interpretation are clearly customer protection initiatives, the DSIO no action letter is not. This no action letter would allow FCMs to keep money in segregated customer accounts that actually would not be readily available in a crisis. Thus, while it may appear that an FCM had considerable funds available to settle customer accounts during a market dislocation, in fact that would be only be an illusion; a portion of those funds could be locked down behind the prime money market funds' gates and therefore not actually be available when needed.

I do not think that the staff of the Commission should be supporting this kind of "window dressing"—giving the impression of greater security than there actually is. If the funds are not suitable investments for customer funds, then they are not suitable for the additional capital that the FCMs put in those accounts to protect against potential shortfalls. Having lived through bankruptcies, such as MF Global and Peregrine, I have a healthy respect for the importance of having strong clearing members with a large cushion of funds that can be accessed when needed. This no action letter undermines that effort. Given the importance of this topic to the general public, we should at least have asked for comments or even held a roundtable before making this change. I therefore hope to reexamine this subject in the near future.

[FR Doc. 2016–19210 Filed 8–11–16; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Training of Interpreters for Individuals Who Are Deaf or Hard of Hearing and Individuals Who Are Deaf-Blind Program; Correction

Catalog of Federal Domestic Assistance (CFDA) Number: 84.160C.

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice; correction.

SUMMARY: On July 25, 2016, we published in the **Federal Register** (81 FR 48409) a notice inviting applications (NIA) for new awards for fiscal year (FY) 2016 for the Training of Interpreters for Individuals Who Are Deaf or Hard of Hearing and Individuals Who Are Deaf-blind program. That notice incorrectly stated that match in the amount of 10 percent was required in order for applicants to meet the required cost match. This document corrects the error.

FOR FURTHER INFORMATION CONTACT: Kristen Rhinehart-Fernandez, U.S. Department of Education, 400 Maryland Avenue SW., Room 5062, Potomac Center Plaza, Washington, DC 20202–2800. Telephone: (202) 245–6103 or by email: *Kristen.Rhinehart@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service, toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: This document corrects the percentage of the required cost match. All other requirements and conditions stated in the NIA remain the same.

Corrections

In the **Federal Register** of July 25, 2016 (81 FR 48409), on page 48409, in the third column, we revise the section "2. Cost Sharing or Matching" to read as follows: "2. *Cost Sharing or Matching:* The Commissioner may award grants to public or private nonprofit agencies or organizations to pay part of the costs for interpreter training programs (section 302(f)(1)(A) of the Rehabilitation Act of 1973). Therefore, in order to be considered for funding, applicants must identify in the application budget and budget narrative a percentage of match towards the total cost of the project. It is up to the applicant to determine an appropriate percentage for the match contribution. To calculate match, applicants may use the match-calculator available at: *https://rsa.ed.gov/match-calculator.cfm.*"

Program Authority: 29 U.S.C. 772(f).

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: August 9, 2016.

Sue Swenson,

Acting Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2016–19269 Filed 8–11–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Training of Interpreters for Individuals Who Are Deaf or Hard of Hearing and Individuals Who Are Deaf-Blind Program

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice.

Overview Information

Training of Interpreters for Individuals Who Are Deaf or Hard of Hearing and Individuals Who Are Deaf-Blind Program Notice inviting applications for new awards for fiscal year (FY) 2016.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.160D.

DATES

Applications Available: August 12, 2016.

Deadline for Transmittal of Applications: September 12, 2016.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: Under the Rehabilitation Act of 1973 (Rehabilitation Act), as amended by the Workforce Innovation and Opportunity Act, the Rehabilitation Services Administration (RSA) makes grants to public and private nonprofit agencies and organizations, including institutions of higher education (IHE), to establish interpreter training programs or to provide financial assistance for ongoing interpreter training programs to train a sufficient number of qualified interpreters throughout the country. The grants are designed to train interpreters to effectively interpret and transliterate using spoken, visual, and tactile modes of communication; ensure the maintenance of the interpreting skills of qualified interpreters; and provide opportunities for interpreters to improve their skills in order to meet both the highest standards approved by certifying associations and the communication needs of individuals who are deaf or hard of hearing and individuals who are deaf-blind.

Priority: This priority is from the notice of final priority for this program (NFP) published elsewhere in this issue of the **Federal Register**.

Absolute Priority: For FY 2016, this priority is an absolute priority. Under 34 CFR 75.105(c)(3), we consider only applications that meet this priority.

This priority is:

Interpreter Training in Specialized Areas

Program Authority: 29 U.S.C. 772(f).

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The regulations for this program in 34 CFR part 396. (e) The NFP.

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized American Indian tribes.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $1,600,000.

Contingent upon availability of funds and the quality of applications, we may make additional awards in FY 2017 and FY 2018 from the list of unfunded applications from this competition.

Estimated Range of Awards: $375,000–$400,000.

Estimated Average Size of Awards: $385,000.

Maximum Award Amount: We will reject any application that proposes a budget exceeding $400,000 for a single budget period of 12 months.

Estimated Number of Awards: 4.

Note: The Department is not bound by any estimates in this notice.

Note: Under 34 CFR 75.562(c), an indirect cost reimbursement on a training grant is limited to the recipient's actual indirect costs, as determined by its negotiated indirect cost rate agreement, or eight percent of a modified total direct cost base, whichever amount is less. Indirect costs in excess of the limit may not be charged directly, used to satisfy matching or cost-sharing requirements, or charged to another Federal award.

Project Period: Up to 60 months.

Continuing the Fourth and Fifth Years of the Project: In deciding whether to continue funding the Training of Interpreters for Individuals Who Are Deaf or Hard of Hearing and Individuals Who Are Deaf-Blind program for the fourth and fifth years, the Department will conduct a one-day intensive review meeting during the third quarter of the third year of the project period. Specific details of this review and evaluation criteria will be determined post-award.

III. Eligibility Information

1. *Eligible Applicants:* States and public or nonprofit agencies and organizations, including American Indian tribes and IHEs.

2. *Cost Sharing or Matching:* The Commissioner may award grants to public or private nonprofit agencies or organizations to pay part of the costs for interpreter training programs (section 302(f)(1)(A) of the Rehabilitation Act of 1973). Therefore, in order to be considered for funding, applicants must identify in the application budget and budget narrative a percentage of match towards the total cost of the project. It is up to the applicant to determine an appropriate percentage for the match contribution. To calculate match, applicants may use the match-calculator available at: *https://rsa.ed.gov/match-calculator.cfm.*

IV. Application and Submission Information

1. *Address to Request Application Package:* You can obtain an application package via the Internet or from the Education Publications Center (ED Pubs). To obtain a copy via the Internet, use the following address: *www.ed.gov/fund/grant/apply/grantapps/index.html.* To obtain a copy from ED Pubs, write, fax, or call: ED Pubs, U.S. Department of Education, P.O. Box 22207, Alexandria, VA 22304. Telephone, toll free: 1–877–433–7827. FAX: (703) 605–6794. If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call, toll free: 1–877–576–7734.

You can contact ED Pubs at its Web site, also: *www.EDPubs.gov* or at its email address: *edpubs@inet.ed.gov.*

If you request an application package from ED Pubs, be sure to identify this program or competition as follows: CFDA number 84.160D.

Individuals with disabilities can obtain a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) by contacting the person or team listed under *Accessible Format* in section VIII of this notice.

2. *Content and Form of Application Submission:* Requirements concerning the content and form of an application, together with the forms you must submit, are in the application package for this competition.

Page Limit: The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. Because of the limited time available to review applications and make a recommendation for funding, we strongly encourage applicants to limit the application narrative to no more than 45 pages, using the following standards:

- A "page" is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial. An application submitted in any other font (including Times Roman or Arial Narrow) will not be accepted.

In addition to the page-limit guidance on the application narrative section, we recommend that you adhere to the following page limits, using the standards listed above: (1) The abstract should be no more than one page, (2) the resumes of key personnel should be no more than two pages per person, and (3) a bibliography should be no more than three pages. Appendix A must include: (1) A logic model; and (2) person-loading charts and timelines. There are no page limits or standards for materials in Appendix A. The only optional materials that will be accepted are letters of support. Please note that our reviewers are not required to read optional materials.

Please note that any funded applicant's application abstract will be made available to the public.

3. *Submission Dates and Times:* *Applications Available:* August 12, 2016.

Date of Pre-Application Teleconference: Interested parties are invited to submit questions to the following email address: *TSPDgrants@ed.gov.* In the subject line of the email, please insert the text "CFDA 84.160D". Interested parties are invited to participate in a pre-application teleconference with staff from the Department on August 18, 2016 at 11:30 a.m. Eastern Time. The teleconference number is: 888–843–6165, and the passcode is: 7905685. For further information about the pre-application teleconference, contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice.

Deadline for Transmittal of Applications: September 12, 2016.

Applications for grants under this competition must be submitted electronically using the *Grants.gov* Apply site (*Grants.gov*). For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer to *Other Submission Requirements* in section IV of this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

4. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. However, under 34 CFR 79.8(a), we waive intergovernmental review in order to make an award by the end of FY 2016.

5. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. *Data Universal Numbering System Number, Taxpayer Identification Number, and System for Award Management:* To do business with the Department of Education, you must—

a. Have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN);

b. Register both your DUNS number and TIN with the System for Award Management (SAM), the Government's primary registrant database;

c. Provide your DUNS number and TIN on your application; and

d. Maintain an active SAM registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

You can obtain a DUNS number from Dun and Bradstreet at the following Web site: *http://fedgov.dnb.com/webform.* A DUNS number can be created within one to two business days.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow two to five weeks for your TIN to become active.

The SAM registration process can take approximately seven business days, but may take upwards of several weeks, depending on the completeness and accuracy of the data you enter into the SAM database. Thus, if you think you might want to apply for Federal financial assistance under a program administered by the Department, please allow sufficient time to obtain and register your DUNS number and TIN. We strongly recommend that you register early.

Note: Once your SAM registration is active, it may be 24 to 48 hours before you can access the information in, and submit an application through, *Grants.gov.*

If you are currently registered with SAM, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS number is correct. Also note that you will need to update your registration annually. This may take three or more business days.

Information about SAM is available at *www.SAM.gov.* To further assist you with obtaining and registering your DUNS number and TIN in SAM or updating your existing SAM account, we have prepared a SAM.gov Tip Sheet, which you can find at: *http://www2.ed.gov/fund/grant/apply/sam-faqs.html.*

In addition, if you are submitting your application via *Grants.gov*, you must (1) be designated by your organization as an Authorized Organization Representative (AOR); and (2) register yourself with *Grants.gov* as an AOR. Details on these steps are outlined at the following *Grants.gov* Web page: *www.grants.gov/web/grants/register.html.*

7. *Other Submission Requirements:* Applications for grants under this competition must be submitted electronically unless you qualify for an exception to this requirement in accordance with the instructions in this section.

a. Electronic Submission of Applications

Applications for grants under the Training of Interpreters for Individuals Who Are Deaf or Hard of Hearing and Individuals Who Are Deaf-Blind Program must be submitted electronically using the Governmentwide *Grants.gov* Apply site at *www.Grants.gov.* Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not email an electronic copy of a grant application to us.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement *and* submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement.*

You may access the electronic grant application for the Training of Interpreters for Individuals Who Are Deaf or Hard of Hearing and Individuals Who Are Deaf-Blind Program at *www.Grants.gov.* You must search for the downloadable application package for this competition by the CFDA number. Do not include the CFDA number's alpha suffix in your search (*e.g.*, search for 84.160, not 84.160D).

Please note the following:

- When you enter the *Grants.gov* site, you will find information about submitting an application electronically through the site, as well as the hours of operation.
- Applications received by *Grants.gov* are date and time stamped. Your application must be fully uploaded and submitted and must be date and time stamped by the *Grants.gov* system no later than 4:30:00 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not accept your application if it is received—that is, date and time stamped by the *Grants.gov* system—after 4:30:00 p.m., Washington, DC time, on the application deadline date. We do not consider an application that does not comply with the deadline requirements. When we retrieve your application from *Grants.gov*, we will notify you if we are rejecting your application because it was date and time stamped by the *Grants.gov* system after 4:30:00 p.m., Washington, DC time, on the application deadline date.
- The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through *Grants.gov.*
- You should review and follow the Education Submission Procedures for submitting an application through *Grants.gov* that are included in the application package for this competition to ensure that you submit your application in a timely manner to the *Grants.gov* system. You can also find the Education Submission Procedures pertaining to *Grants.gov* under News and Events on the Department's G5 system home page at *www.G5.gov.* In addition, for specific guidance and procedures for submitting an application through *Grants.gov*, please refer to the *Grants.gov* Web site at: *www.grants.gov/web/grants/applicants/apply-for-grants.html.*
- You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.
- You must submit all documents electronically, including all information you typically provide on the following forms: The Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.
- You must upload any narrative sections and all other attachments to your application as files in a read-only, non-modifiable Portable Document Format (PDF). Do not upload an interactive or fillable PDF file. If you upload a file type other than a read-only, non-modifiable PDF (*e.g.*, Word, Excel, WordPerfect, etc.) or submit a password-protected file, we will not review that material. Please note that this could result in your application not being considered for funding because the material in question—for example, the application narrative—is critical to a

meaningful review of your proposal. For that reason, it is important to allow yourself adequate time to upload all material as PDF files. The Department will not convert material from other formats to PDF.

- Your electronic application must comply with any page-limit requirements described in this notice.
- After you electronically submit your application, you will receive from *Grants.gov* an automatic notification of receipt that contains a *Grants.gov* tracking number. This notification indicates receipt by *Grants.gov* only, not receipt by the Department. *Grants.gov* will also notify you automatically by email if your application met all the *Grants.gov* validation requirements or if there were any errors (such as submission of your application by someone other than a registered Authorized Organization Representative or inclusion of an attachment with a file name that contains special characters). You will be given an opportunity to correct any errors and resubmit, but you must still meet the deadline for submission of applications.

Once your application is successfully validated by *Grants.gov*, the Department will retrieve your application from *Grants.gov* and send you an email with a unique PR/Award number for your application.

These emails do not mean that your application is without any disqualifying errors. While your application may have been successfully validated by *Grants.gov*, it must also meet the Department's application requirements as specified in this notice and in the application instructions. Disqualifying errors could include, for instance, failure to upload attachments in a read-only, non-modifiable PDF; failure to submit a required part of the application; or failure to meet applicant eligibility requirements. It is your responsibility to ensure that your submitted application has met all of the Department's requirements.

- We may request that you provide us original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues with the Grants.gov System: If you are experiencing problems submitting your application through *Grants.gov*, please contact the *Grants.gov* Support Desk, toll free, at 1–800–518–4726. You must obtain a *Grants.gov* Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the *Grants.gov* system, we will grant you an extension until 4:30:00 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30:00 p.m., Washington, DC time, on the application deadline date, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice and provide an explanation of the technical problem you experienced with *Grants.gov*, along with the *Grants.gov* Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the *Grants.gov* system and that the problem affected your ability to submit your application by 4:30:00 p.m., Washington, DC time, on the application deadline date. We will contact you after we determine whether your application will be accepted.

Note: The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the *Grants.gov* system. We will not grant you an extension if you failed to fully register to submit your application to *Grants.gov* before the application deadline date and time or if the technical problem you experienced is unrelated to the *Grants.gov* system.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through the *Grants.gov* system because—

- You do not have access to the Internet; or
- You do not have the capacity to upload large documents to the *Grants.gov* system;

and

- No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevents you from using the Internet to submit your application.

If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: Kristen Rhinehart-Fernandez, U.S. Department of Education, 400 Maryland Avenue SW., Room 5062, Potomac Center Plaza, Washington, DC 20202–2800. FAX: (202) 245–7591.

Your paper application must be submitted in accordance with the mail or hand-delivery instructions described in this notice.

b. Submission of Paper Applications by Mail

If you qualify for an exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier) your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.160D), LBJ Basement Level 1, 400 Maryland Avenue SW., Washington, DC 20202–4260.

You must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

We will not consider applications postmarked after the application deadline date.

c. Submission of Paper Applications by Hand Delivery

If you qualify for an exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.160D), 550 12th

Street SW., Room 7039, Potomac Center Plaza, Washington, DC 20202–4260.

The Application Control Center accepts hand deliveries daily between 8:00 a.m. and 4:30:00 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from 34 CFR 75.210 of EDGAR and are listed in the application package.

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Risk Assessment and Special Conditions:* Consistent with 2 CFR 200.205, before awarding grants under this competition, the Department conducts a review of the risks posed by applicants. Under 2 CFR 3474.10, the Secretary may impose special conditions and, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

4. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $150,000), under 2 CFR 200.205(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through SAM. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN), or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

(c) Under 34 CFR 75.250(b), the Secretary may provide a grantee with additional funding for data collection analysis and reporting. In this case, the Secretary establishes a data collection period.

4. *Performance Measures:* The Government Performance and Results Act of 1993 (GPRA) directs Federal departments and agencies to improve the effectiveness of their programs by engaging in strategic planning, setting outcome-related goals for programs, and measuring program results against those goals.

The performance measures for this program are as follows:

(1) The number of working interpreters enrolled in specialized training.

(2) The number and percentage of working interpreters who successfully complete specialized training.

(3) The number and percentage of working interpreters who successfully completed specialized training who subsequently obtained employment in the area(s) for which they were prepared.

(4) The number and percentage of working interpreters who successfully completed specialized training who subsequently advanced in employment in the areas(s) for which they were prepared.

5. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: Whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Agency Contact

FOR FURTHER INFORMATION CONTACT: Kristen Rhinehart-Fernandez, U.S. Department of Education, 400 Maryland Avenue SW., Room 5062, Potomac Center Plaza, Washington, DC 20202–2800. Telephone: (202) 245–6103 or by email: *Kristen.Rhinehart@ed.gov.*

If you use a TDD or a TTY, call the Federal Relay Service, toll free, at 1–800–877–8339.

VIII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site, you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: August 9, 2016.

Sue Swenson,

Acting Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2016–19270 Filed 8–11–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Catalog of Federal Domestic Assistance (CFDA) Number: 84.184C]

Reopening; Applications for New Awards; Promoting Student Resilience

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Notice.

SUMMARY: On June 23, 2016, we published in the **Federal Register** (81 FR 40877) a notice inviting applications (NIA) for the Promoting Student Resilience fiscal year (FY) 2016 competition. The NIA established a deadline date of July 25, 2016, for the transmittal of applications. This notice reopens the competition until August 19, 2016.

DATES: Deadline for Transmittal of Applications: August 19, 2016.

SUPPLEMENTARY INFORMATION: We are reopening this competition in order to allow applicants more time to prepare and submit their applications.

Note: All information in the NIA for this competition remains the same, except for the deadline for the transmittal of applications.

Program Authority: 20 U.S.C. 7131, and Title III of Division H of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113).

FOR FURTHER INFORMATION CONTACT: Deirdra Hilliard, U.S. Department of Education, 400 Maryland Avenue SW., Room 3E–249, Washington, DC 20202–6450. Telephone: (202) 453–6726 or by email: *deirdra.hilliard@ed.gov.*

If you use a telecommunications device for the deaf or a text telephone, call the Federal Relay Service, toll free, at 1–800–877–8339.

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT** in this notice.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: August 9, 2016.

Ann Whalen,

Senior Advisor to the Secretary Delegated the Duties of Assistant Secretary for Elementary and Secondary Education.

[FR Doc. 2016–19254 Filed 8–11–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Energy Savings Performance Contract Energy Sales Agreement; Request for Information

AGENCY: Federal Energy Management Program, Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of availability and request for information.

SUMMARY: The Federal Energy Management Program Office (FEMP), within the U.S. Department of Energy (DOE), published a notice, "Request for Comments on the Tax Treatment of an Energy Savings Performance Contract Energy Sales Agreement," on its Web site to gather information on specific concerns related to the Federal Investment Tax Credit eligibility of a renewable energy project structured as an Energy Savings Performance Contract (ESPC) Energy Sales Agreement (ESA) that could benefit from clarification in the form of guidance issued by the Internal Revenue Service and the U.S. Department of the Treasury.

DATES: Written comments and information are requested on or before September 3, 2016.

ADDRESSES: Interested parties are to submit comments electronically to: *tracy.niro@ee.doe.gov.* Include "August 2016 ESPC Request for Comments" in the subject of the message.

Instructions: All submissions received must include "August 2016 ESPC Request for Comments" in the subject of the message. The notice is available at *www.energy.gov/node/1953536.*

FOR FURTHER INFORMATION CONTACT: Tracy Niro, U.S. Department of Energy, Federal Energy Management Program (EE–2L), 1000 Independence Avenue SW., Washington, DC 20585; email: *Tracy.Niro@ee.doe.gov.*

SUPPLEMENTARY INFORMATION: FEMP published a request for comment (RFC) to gather information on the potential for an Energy Savings Performance Contract Energy Sales Agreement (ESPC ESA) project to qualify as a service contract under 26 U.S.C. 7701(e) and thus remain eligible for the 26 U.S.C. 48 solar investment tax credit (ITC). The RFC requests commenters to identify any specific language included in 26 U.S.C. 7701(e)(4)(A)(i)–(iv) that could benefit from clarification in the form of guidance from Internal Revenue Service (IRS) and the U.S. Department of Treasury (Treasury). The RFC is available at *www.energy.gov/node/1953536.* The RFC is a continuation of the issues presented in the Federal Energy Management Program's (FEMP) *Request for Comments on Including Onsite Renewable Energy Generation under Energy Savings Performance Contracts,* issued on February 2, 2016, *available at http://energy.gov/eere/femp/downloads/request-comments-including-onsite-renewable-energy-generation-under-energy.*

FEMP invites all interested parties to submit in writing by September 3, 2016, comments and information on matters addressed in the notice.

Issued in Washington, DC, on August 5, 2016.

Hayes Jones,

Operations Supervisor, Federal Energy Management Program.

[FR Doc. 2016–19232 Filed 8–11–16; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9028–5]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7146 or *http://www.epa.gov/nepa.*

Weekly receipt of Environmental Impact Statements (EISs)

Filed 08/01/2016 Through 08/05/2016

Pursuant to 40 CFR 1506.9.

Notice: Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *http://www.epa.gov/compliance/nepa/eisdata.html.*

EIS No. 20160183, Final, USFS, CO, Arapahoe Basin Ski Area Projects, Review Period Ends: 09/19/2016, Contact: Matthew Ehrman 970–945–3212.

EIS No. 20160184, Draft, DOC, 00, Programmatic—Central Region of the Nationwide Public Safety Broadband Network, Comment Period Ends: 10/11/2016, Contact: Robert Scinta 202–870–3923.

EIS No. 20160185, Draft, BLM, CO, Gunnison Sage-Grouse Rangewide Resource Management Plan Amendment, Comment Period Ends: 11/10/2016, Contact: Bridget Clayton 970–244–3045.

Dated: August 9, 2016.

Dawn Roberts,

Management Analyst, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2016–19247 Filed 8–11–16; 8:45 am]

BILLING CODE 6560–50–P

FARM CREDIT ADMINISTRATION

[NV–16–14]

Equal Employment Opportunity and Diversity

AGENCY: Farm Credit Administration.

ACTION: Policy statement.

SUMMARY: The Farm Credit Administration (FCA) Board recently updated its Policy Statement on Equal Employment Opportunity and Diversity.

DATES: *Effective Date:* August 8, 2016.

FOR FURTHER INFORMATION CONTACT: Thais Burlew, Director of Equal Employment Opportunity and Inclusion, Farm Credit Administration, 1501 Farm Credit Drive, McLean Virginia 22102–5090, (703) 883–4290, TTY (703) 883–4352.

SUPPLEMENTARY INFORMATION: While not required by law, the Equal Employment Opportunity Commission (EEOC) has determined that reissuance of an agency's EEO policy statement each fiscal year is a symbol of the agency leadership's commitment to EEO and Diversity principles. The FCA conducted its annual review of Policy Statement FCA–PS–62 on Equal Employment Opportunity (EEO) and Diversity. The policy has been slightly edited at EEOC's recommendation to indicate that FCA begins prompt, thorough, and impartial investigations within 10 days of receiving notice of harassment allegations.

The text of the updated Policy Statement is set forth below in its entirety. All FCA Board policy statements may be viewed on FCA's Web site. From *www.fca.gov,* select "Laws & Regulations," then select "FCA Handbook," then select "FCA Board Policy Statements."

Equal Employment Opportunity and Diversity

FCA–PS–62

Effective Date: August 8, 2016.

Effect on Previous Action: Replaces FCA–PS–62 [NV15–10] dated August 18, 2015 (80 FR 51806, 8/26/15).

Source of Authority: Title VII of the Civil Rights Act of 1964, as amended (42 U.S.C. 2000e *et seq.*); Age Discrimination in Employment Act (29 U.S.C. 621 *et seq.*); Rehabilitation Act of 1973, as amended (29 U.S.C. 721 *et seq.*); Equal Pay Act of 1974 (29 U.S.C. 206(d)); Civil Service Reform Act of 1978 (5 U.S.C. 3112); Notification and Federal Employee Antidiscrimination and Retaliation Act of 2002 (No FEAR Act) (5 U.S.C. 2301); Genetic Information Nondiscrimination Act of 2008 (42 U.S.C. 2000ff *et seq.*); section 5.9 of the Farm Credit Act of 1971, as amended (12 U.S.C. 2243); Executive Order 11478 (Equal Employment Opportunity in the Federal Government), as amended by Executive Orders 13087 and 13152 to include prohibitions on discrimination based on sexual orientation and status as a parent; Executive Order 13166 (Improving Access to Services for Persons with Limited English Proficiency); 29 CFR part 1614; Equal Employment Opportunity Commission Management Directives. The Farm Credit Administration Board hereby adopts the following policy statement:

Purpose

The Farm Credit Administration (FCA or Agency) Board reaffirms its commitment to Equal Employment Opportunity (EEO) and Diversity (EEOD) and its belief that all FCA employees should be treated with dignity and respect. The Board also provides guidance to Agency management and staff for deciding and taking action in these critical areas.

Importance

Unquestionably, the employees who comprise the FCA are its most important resource. The Board fully recognizes that the Agency draws its strength from the dedication, experience, and diversity of its employees. The Board is firmly committed to taking whatever steps are needed to protect the rights of its staff and to carrying out programs that foster the development of each employee's potential. We believe an investment in efforts that strongly promote EEOD will prevent the conflict and the high costs of correction for taking no, or inadequate, action in these areas.

The Farm Credit Administration (FCA) Board Adopts the Following Policy Statement: It is the policy of the FCA to prohibit discrimination in Agency policies, program practices, and operations. Employees, applicants for employment, and members of the public who seek to take part in FCA programs, activities, and services will be treated fairly. The FCA Board Chairman and Chief Executive Officer (CEO) is ultimately responsible for ensuring that FCA meets all EEOD requirements and initiatives in accordance with laws and regulations, to maintain a workplace that is free from discrimination and that values all employees. FCA, under the appropriate laws and regulations, will:

- Ensure equal employment opportunity based on merit and qualification, without discrimination because of race, color, religion, sex (including sexual orientation), age (40 or older), national origin, disability, status as a parent, genetic information, or filing of a complaint, participation in discrimination or harassment complaint proceedings, or other opposition to discrimination;
- Provide for the prompt and fair consideration of complaints of discrimination;
- Make reasonable accommodations for qualified applicants for employment and employees with physical or mental disabilities under law;
- Make reasonable accommodations based on applicants' and employees' religious beliefs or practices, consistent with Title VII;
- Provide an environment free from harassment to all employees;
- Create and maintain an organizational culture that recognizes, values, and supports employee and public diversity and inclusion;
- Develop objectives within the Agency's operation and strategic planning process to meet the goals of EEOD and this policy;
- Implement affirmative programs to carry out this policy within the Agency; and
- To the extent practicable, seek to encourage the Farm Credit System to continue its efforts to promote and increase diversity.

Diversity and Inclusion

The FCA intends to be a model employer. That is, as far as possible, FCA will build and maintain a workforce that reflects the rich diversity of individual differences evident throughout this Nation. The Board views individual differences as complementary and believes these differences enrich our organization. When individual differences are respected, recognized, and valued, diversity becomes a powerful force that can contribute to achieving superior results. Therefore, we will create, maintain, and continuously improve on an organizational culture that fully recognizes, values, and supports employee diversity. The Board is committed to promoting and supporting an inclusive environment that provides to all employees, individually and collectively, the chance to work to their full potential in the pursuit of the Agency's mission. We will provide everyone the opportunity to develop to his or her fullest potential. When a barrier to someone achieving this goal exists, we will strive to remove this barrier.

Affirmative Employment

The Board reaffirms its commitment to ensuring FCA conducts all of its employment practices in a nondiscriminatory manner. The Board expects full cooperation and support from everyone associated with recruitment, selection, development, and promotion to ensure such actions are free of discrimination. All employees will be evaluated on their EEOD achievements as part of their overall job performance. Though staff commitment is important, the role of supervisors is paramount to success. Agency supervisors must be coaches and are responsible for helping all employees develop their talents and give their best efforts in contributing to the mission of the FCA.

Workplace Harassment

It is the policy of the FCA to provide a work environment free from unlawful discrimination in any form, and to protect all employees from any form of harassment, either physical or verbal. The FCA will not tolerate harassment in the workplace for any reason. The FCA also will not tolerate retaliation against any employee for reporting harassment or for aiding in any inquiry about reporting harassment. FCA begins prompt, thorough, and impartial investigations within 10 days of receiving notice of harassment allegations.

Disabled Veterans Affirmative Action Program (DVAAP)

A disabled veteran is defined as someone who is entitled to compensation under the laws administered by the Veterans Administration or someone who was discharged or released from active duty because of a service-connected disability. The FCA is committed to increasing the representation of disabled veterans within its organization. Our Nation owes a debt to those veterans who served their country, especially those who were disabled because of service. To honor these disabled veterans, the FCA shall place emphasis on making vacancies known to and providing opportunities for employing disabled veterans.

Dated this 8th day of August 2016 by order of the Board.

Dated: August 8, 2016.

Dale L. Aultman,

Secretary, Farm Credit Administration Board.

[FR Doc. 2016–19196 Filed 8–11–16; 8:45 am]

BILLING CODE 6705–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice to All Interested Parties of the Termination of the Receivership of 10474 First Federal Bank, Lexington, Kentucky

Notice Is Hereby Given that the Federal Deposit Insurance Corporation ("FDIC") as Receiver for First Federal Bank, Lexington, Kentucky ("the Receiver") intends to terminate its receivership for said institution. The FDIC was appointed receiver of First Federal Bank on April 19, 2013. The liquidation of the receivership assets has been completed. To the extent permitted by available funds and in accordance with law, the Receiver will be making a final dividend payment to proven creditors.

Based upon the foregoing, the Receiver has determined that the continued existence of the receivership will serve no useful purpose. Consequently, notice is given that the receivership shall be terminated, to be effective no sooner than thirty days after the date of this Notice. If any person wishes to comment concerning the termination of the receivership, such comment must be made in writing and sent within thirty days of the date of this Notice to: Federal Deposit Insurance Corporation, Division of Resolutions and Receiverships, Attention: Receivership Oversight Department 34.6, 1601 Bryan Street, Dallas, TX 75201.

No comments concerning the termination of this receivership will be considered which are not sent within this time frame.

Dated: August 8, 2016.

Federal Deposit Insurance Corporation.

Ralph E. Frable,

Assistant Executive Secretary.

[FR Doc. 2016–19101 Filed 8–11–16; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meetings

AGENCY: Federal Election Commission.

DATE AND TIME: Tuesday, August 16, 2016 at 10:00 a.m.

PLACE: 999 E Street NW., Washington, DC (Ninth Floor).

STATUS: This meeting will be open to the public.

ITEMS TO BE DISCUSSED:

Correction and Approval of Minutes for June 30, 2016
Draft Advisory Opinion 2016–08: *eBundler.com,* LLC
REG 2013–01: Draft Notice of Proposed Rulemaking on Technological Modernization
REG 2014–10: Implementing the Consolidated and Further Continuing
Appropriations Act, 2015
REG 2016–03: Political Party Rules
Proposal to Rescind Advisory Opinion 2006–15 (TransCanada)
Management and Administrative Matters

Individuals who plan to attend and require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Shawn Woodhead Werth, Secretary and Clerk, at (202) 694–1040, at least 72 hours prior to the meeting date.

PERSON TO CONTACT FOR INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Shawn Woodhead Werth,

Secretary and Clerk of the Commission.

[FR Doc. 2016–19305 Filed 8–10–16; 11:15 am]

BILLING CODE 6715–01–P

FEDERAL ELECTION COMMISSION

[Notice 2016–08]

Filing Dates for the Hawaii Special Election in the 1st Congressional District

AGENCY: Federal Election Commission.

ACTION: Notice of filing dates for special election.

SUMMARY: Hawaii has scheduled a special general election on November 8, 2016, to fill the U.S. House of Representatives seat in the 1st Congressional District of the late Representative Mark Takai.

Committees required to file reports in connection with the Special General Election on November 8, 2016, shall file a 12-day Pre-General Report, and a 30-day Post-General Report.

FOR FURTHER INFORMATION CONTACT: Ms. Elizabeth S. Kurland, Information Division, 999 E Street NW., Washington, DC 20463; Telephone: (202) 694–1100; Toll Free (800) 424–9530.

SUPPLEMENTARY INFORMATION:

Principal Campaign Committees

All principal campaign committees of candidates who participate in the Hawaii Special General Election shall file a 12-day Pre-General Report on October 27, 2016; and a Post-General Report on December 8, 2016. (See chart below for the closing date for each report.)

Note that these reports are in addition to the campaign committee's regular quarterly filings. (See chart below for the closing date for each report).

Unauthorized Committees (PACs and Party Committees)

Political committees filing on a quarterly basis in 2016 are subject to special election reporting if they make previously undisclosed contributions or expenditures in connection with the Hawaii Special General Election by the close of books for the applicable report(s). (See chart below for the closing date for each report.)

Committees filing monthly that make contributions or expenditures in connection with the Hawaii Special General Election will continue to file according to the monthly reporting schedule.

Additional disclosure information in connection with the Hawaii Special General Election may be found on the FEC Web site at *http://www.fec.gov/info/report_dates.shtml.*

Disclosure of Lobbyist Bundling Activity

Principal campaign committees, party committees and Leadership PACs that are otherwise required to file reports in connection with the special general election must simultaneously file FEC Form 3L if they receive two or more bundled contributions from lobbyists/registrants or lobbyist/registrant PACs that aggregate in excess of the $17,600 during the special election reporting periods. (See chart below for closing date of each period.) 11 CFR 104.22(a)(5)(v), (b).

CALENDAR OF REPORTING DATES FOR HAWAII SPECIAL GENERAL ELECTION COMMITTEES INVOLVED IN THE SPECIAL GENERAL ELECTION (11/08/16) MUST FILE

Report	Close of books [1]	Reg./Cert. & overnight mailing deadline	Filing deadline
Pre-General	10/19/16	10/24/16	10/27/16
Post-General	11/28/16	12/08/16	12/08/16
Year-End	12/31/16	01/31/17	01/31/17

[1] The reporting period always begins the day after the closing date of the last report filed. If the committee is new and has not previously filed a report, the first report must cover all activity that occurred before the committee registered as a political committee up through the close of books for the first report due.

On behalf of the Commission,

Matthew S. Petersen,

Chairman, Federal Election Commission.

[FR Doc. 2016–19205 Filed 8–11–16; 8:45 am]

BILLING CODE 6715–01–P

FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Federal Trade Commission ("Commission" or "FTC").

ACTION: Notice.

SUMMARY: The information collection requirements described below will be submitted to the Office of Management and Budget ("OMB") for review, as required by the Paperwork Reduction Act ("PRA"). The FTC is seeking public comments on its proposal to extend for an additional three years the current PRA clearance for information collection requirements in its Antitrust Improvements Act Rules ("HSR Rules") and corresponding Notification and Report Form for Certain Mergers and Acquisitions ("Notification and Report

Form''). That clearance expires on December 31, 2016.

DATES: Comments must be filed by October 11, 2016.

ADDRESSES: Interested parties may file a comment online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write ''HSR PRA Clearance Extension, P169300'' on your comment and file your comment online at *https://ftcpublic.commentworks.com/ftc/hsrrulespra,* by following the instructions on the web-based form. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex J), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Robert L. Jones, Assistant Director, Premerger Notification Office, Bureau of Competition, Federal Trade Commission, Room CC–5301, 600 Pennsylvania Ave. NW., Washington, DC 20580, or by telephone to (202) 326–2740.

SUPPLEMENTARY INFORMATION: Under the PRA, 44 U.S.C. 3501–3521, federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. ''Collection of information'' means agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. 44 U.S.C. 3502(3); 5 CFR 1320.3(c). As required by section 3506(c)(2)(A) of the PRA, the FTC is providing this opportunity for public comment before requesting that OMB extend the existing PRA clearance for the HSR Rules and Notification and Report Form, 16 CFR part 801—803 (OMB Control Number 3084–0005).

Pursuant to Section 3506(c)(2)(A), the FTC invites comments on: (1) Whether the disclosure requirements are necessary, including whether the information will be practically useful; (2) the accuracy of our burden estimates, including whether the methodology and assumptions used are valid; (3) how to improve the quality, utility, and clarity of the disclosure requirements; and (4) how to minimize the burden of providing the required information to consumers.

Background Information: Section 7A of the Clayton Act (''Act''), 15 U.S.C. 18a, as amended by the Hart-Scott-Rodino Antitrust Improvements Act of 1976, Public Law 94–435, 90 Stat. 1390, requires all persons contemplating certain mergers or acquisitions to file notification with the Commission and the Assistant Attorney General and to wait a designated period of time before consummating such transactions. Congress empowered the Commission, with the concurrence of the Assistant Attorney General, to require ''that the notification . . . be in such form and contain such documentary material and information . . . as is necessary and appropriate'' to enable the agencies ''to determine whether such acquisitions may, if consummated, violate the antitrust laws.'' 15 U.S.C. 18a(d). Congress similarly granted rulemaking authority to, *inter alia,* ''prescribe such other rules as may be necessary and appropriate to carry out the purposes of this section.'' *Id.*

Pursuant to that section, the Commission, with the concurrence of the Assistant Attorney General, developed the HSR Rules and the corresponding Notification and Report Form. The following discussion presents the FTC's PRA burden analysis regarding completion of the Notification and Report Form.

Burden Statement: The following burden estimates are primarily based on FTC data concerning the number of HSR filings and staff's informal consultations with leading HSR counsel.

Estimated Total Annual Hours

In fiscal year 2015, there were 3,585 non-index filings and just one index filing.[1] Based on an average annual increase of 27% in fiscal years 2013—2015, FTC staff projects a total of 4,553 non-index filings in fiscal year 2016. With index filings not having demonstrated a singular direction over the same span, however, staff instead bases its estimate on a rough average of the number of such filings over that same interval (fiscal years 2013—2015) to project a total of 10 index filings for fiscal year 2016.[2] Retaining prior assumptions, FTC staff estimates that non-index filings require, on average, approximately 37 hours per filing and that index filings require an average of 2 hours per filing.

Calculating the burden for auto-withdrawal of filings pursuant to § 803.12(b) of the HSR Rules requires an analysis of two potential scenarios. In one scenario, a filing is automatically withdrawn and the acquiring person utilizes the two-day resubmission process under § 803.12(c). In that case, no additional transaction is generated as the acquiring person simply restarts the waiting period on the same transaction. In the second scenario, the parties to a terminated transaction for which the filing is automatically withdrawn do not utilize the two-day resubmission process under § 803.12(c) but later decide to move forward with the transaction. In that case, a new filing is required. Both of these scenarios are rare, as it is very unlikely that a transaction for which the HSR filing is automatically withdrawn during the merger review process (due to the parties' SEC filing indicating that the transaction has been terminated) would be subsequently restarted. Based on experience to date, this would occur approximately once every fifteen years, *i.e.,* a historical frequency of .067 transactions per year. FTC staff believes that this new filing would require the same work and diligence as any new non-index filing. Assuming, then, an average of 37 hours for one transaction, when applied to a historical frequency of .067, this amounts to an annual average of 3 hours, rounded up, for a withdrawn transaction later restarted.

Thus, the total estimated hours burden before adjustments is 168,484 hours [(4,553 non-index filings × 37 hours/each) + (10 index filings × 2 hours/each) + (1 withdrawn transaction later restarted × 3 hours))].

Estimated Total Annual Labor Cost

Using the burden hours (168,484) estimated above and applying an estimated average of $460/hour for executive and/or attorney compensation, staff estimates that the total labor cost associated with the HSR Rules and the Notification and Report Form is approximately $77,502,640.

Estimated Total Annual Non-Labor Cost

The applicable requirements impose minimal start-up costs, as businesses subject to the HSR Rules generally have or obtain necessary equipment for other business purposes. Staff believes that the above requirements necessitate ongoing, regular training so that covered entities stay current and have a clear understanding of federal mandates, but that this would be a small portion of and subsumed within the ordinary training that employees receive apart from that associated with the information collected under the HSR Rules and the corresponding Notification and Report Form.

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[1] ''Index'' filings pertain to banking transactions, and thus would not be affected by the amendments. Index filings are incorporated, however, into the FTC's currently cleared burden estimates (the FTC has jurisdiction over the administration of index filings). They are mentioned here to distinguish them from and to further explain a ''non-index'' filing. Clayton Act Sections 7A(c)(6) and (c)(8) exempt from the requirements of the premerger notification program certain transactions that are subject to the approval of other agencies, but only if copies of the information submitted to these other agencies are also submitted to the Agencies. Thus, parties must submit copies of these ''index'' filings, but completing the task requires significantly less time than non-exempt transactions (which require ''non-index'' filings).

[2] Based on the current rate of such filings this year, as well as the actual number of such filings, respectively, in fiscal years 2014 and 2015, the above estimate likely well exceeds the eventual actual results for fiscal year 2016.

Request for Comment: Pursuant to Section 3506(c)(2)(A), the FTC invites comments on: (1) Whether the disclosure requirements are necessary, including whether the information will be practically useful; (2) the accuracy of our burden estimates, including whether the methodology and assumptions used are valid; (3) how to improve the quality, utility, and clarity of the disclosure requirements; and (4) how to minimize the burden of providing the required information to consumers.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before October 11, 2016. Write "HSR PRA Clearance Extension, P169300" on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including to the extent practicable, on the public Commission Web site, at *http://www.ftc.gov/os/publiccomments.shtm.* As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any "[t]rade secret or any commercial or financial information which is . . . privileged or confidential" as provided in Section 6(f) of the FTC Act 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c).[3] Your comment will be kept confidential only if the FTC General Counsel grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at your comment and file your comment online at *https://ftcpublic.commentworks.com/ftc/hsrrulespra* by following the instructions on the web-based form. When this Notice appears at *http://www.regulations.gov/#!home,* you also may file a comment through that Web site.

If you file your comment on paper, write "HSR PRA Clearance Extension, P169300" on your comment and on the envelope, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex J), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before October 11, 2016. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *http://www.ftc.gov/ftc/privacy.htm.*

David C. Shonka,

Acting General Counsel.

[FR Doc. 2016–19230 Filed 8–11–16; 8:45 am]

BILLING CODE 6750–01–P

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[3] In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0376]

Dietary Supplements: New Dietary Ingredient Notifications and Related Issues; Revised Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the issuance of a revised draft guidance for industry entitled "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues." The revised draft guidance supersedes FDA's July 2011 draft guidance on the same topic. The revised draft guidance, when finalized, will help industry in evaluating whether to submit a premarket safety notification for a new dietary ingredient (NDI), or for a dietary supplement containing an NDI, and in preparing such premarket safety notifications (also referred to as NDI notifications).

DATES: Although you may comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on the draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 11, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2011–D–0376 for "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues; Revised Draft Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Dietary Supplement Programs, Center for Food Safety and Applied Nutrition (HFS–810), Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Ali Abdel-Rahman, Center for Food Safety and Applied Nutrition (HFS–810), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1853.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a revised draft guidance for industry entitled "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues." This draft guidance supersedes the July 2011 draft guidance on this topic (76 FR 39111; July 5, 2011) and is being issued consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent our current thinking on this topic. It will not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

On October 25, 1994, the Dietary Supplement Health and Education Act of 1994 (DSHEA) (Pub. L. 103–417) was signed into law. DSHEA amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding, among other provisions: (1) Section 201(ff) (21 U.S.C. 321(ff)), which defines the term "dietary supplement" and (2) section 413 (21 U.S.C. 350b), which describes requirements for NDIs. Among other things, section 413 of the FD&C Act requires the manufacturer or distributor of an NDI, or of a dietary supplement containing the NDI, to submit a premarket notification to FDA (as delegate for the Secretary of Health and Human Services) at least 75 days before introducing the NDI or dietary supplement into interstate commerce, unless the NDI and any other ingredients in the dietary supplement have been present in the food supply as an article used for food in a form in which the food has not been chemically altered (21 U.S.C. 350b(a)(1)). The notification must contain the information, including any citation to published articles, which is the manufacturer or distributor's basis for concluding that a dietary supplement containing the NDI will reasonably be expected to be safe.

This draft guidance has several purposes. First, it is intended to help dietary supplement manufacturers and distributors decide whether to submit an NDI notification. In addition, the draft guidance is intended to provide recommendations on how to conduct a safety assessment for an NDI notification and what to include in the notification. In question and answer form, the draft guidance presents FDA's views on what qualifies as an NDI; when an NDI notification is required; the procedures for submitting an NDI notification; the types of data and information that manufacturers and distributors should consider when evaluating the safety of a dietary supplement containing an NDI; and what should be included in an NDI notification. In addition, the draft guidance contains questions and answers about parts of the dietary supplement definition (section 201(ff) of the FD&C Act) that can affect whether a particular substance may be marketed as a dietary ingredient in a dietary supplement.

We issued the original version of this draft guidance in the **Federal Register** of July 5, 2011 (the 2011 draft guidance). We gave interested parties an opportunity to submit comments by October 3, 2011. In the **Federal Register** of September 9, 2011 (76 FR 55927), we extended the comment period to December 2, 2011. We received numerous comments on the 2011 draft guidance.

Based on those comments and on meetings with industry and other stakeholders, we realized that the 2011 draft guidance contained gaps and unclear statements that were subject to confusion and misinterpretation. Therefore, we decided to clarify and better explain our thinking on some critical issues, in addition to explaining their public health significance, and to request additional comments on these issues before publishing a final guidance. We have revised certain questions and answers and added a number of new questions and answers.

The major topics on which we have revised or added questions and answers are as follows:

- *Chemical alteration*—Dietary supplements containing an NDI are exempt from the notification requirement when they contain only dietary ingredients that have been present in the food supply as an article used for food in a form in which the food has not been chemically altered. Section IV.B of the revised draft guidance explains FDA's interpretation of "present in the food supply as an article used for food" and the public health basis for that interpretation. In addition, section IV.B has been revised to address the question of what constitutes "chemical alteration" more fully and to explain FDA's reasoning on this issue, as well as discussing additional examples of when chemical alteration occurs and when it does not. Because no guidance document can cover every possible manufacturing scenario, the draft guidance encourages industry to consult with FDA in advance on such matters.
- *Manufacturing changes that create an NDI*—A related issue addressed in section IV.A of the draft guidance is when a manufacturing change alters the structure or properties of an ingredient and creates an NDI for which a notification must be submitted. The revised draft guidance provides examples of manufacturing changes that alter the identity of the ingredient, the key factor in determining whether they also change the regulatory status of the ingredient.
- *Synthetic substances*—Section IV.D of the revised draft guidance contains an expanded discussion clarifying FDA's views on when synthetic copies of botanical and other dietary ingredients qualify as dietary ingredients under the FD&C Act. FDA's thinking is based on the text of section 201(ff)(1) of the FD&C Act, which defines some types of dietary ingredients by identity and others by function.
- *New dietary ingredient definition and list of "grandfathered" dietary ingredients*—In section IV.A of the draft guidance, we revised our response to the question about whether there is an authoritative list of dietary ingredients marketed before October 15, 1994 (a so-called "grandfathered list" or "old dietary ingredient list"). Dietary ingredients marketed before that date are not NDIs and therefore are not subject to the premarket notification requirement in section 413 of the FD&C Act. Although there is currently no authoritative list of "grandfathered" ingredients, the revised answer notes that FDA is prepared to compile such a list based on independent and verifiable data to be submitted by industry. The revised answer also discusses FDA's thinking on the regulatory status of dietary ingredients that would be on such a list, as well as the status of dietary ingredients not on such a list.

We also revised several questions and answers in section IV.A to clarify various matters regarding FDA's interpretation of the terms "marketed" and "dietary ingredient" in section 413(d) of the FD&C Act, which defines an NDI as a dietary ingredient that was not marketed in the United States before October 15, 1994, and we added more examples of documentation that can be used to show that a dietary ingredient was marketed prior to October 15, 1994.

- *Structuring notifications efficiently and relying on data from prior notifications and master files*—We added several questions and answers in section IV.C of this draft guidance to suggest ways manufacturers and distributors can reduce the number of NDI notifications they must file and to clarify when data and information from a previous notification or "master file" may be used in a notification. For example, the answer to a new question clarifies that firms may submit an NDI notification that covers the use of the NDI in multiple dietary supplements and includes safety data for a range of doses and/or differing conditions of use. This answer also explains that a firm may submit a confidential "master file" containing specifications, manufacturing procedures, and other identity information for an NDI, and may incorporate information from the master file into its own NDI notification or may authorize another firm to rely on information from the master file in a notification for a dietary supplement containing the NDI. We also added a question and answer to describe when a firm may rely on data in another notification. In addition, section IV.C now includes a question and answer with six examples distinguishing situations in which separate notifications are required for different dietary supplements containing the same NDI from situations in which a single NDI notification covers multiple dietary supplements containing the same NDI. Finally, section IV.C now clarifies that, although a combination of NDIs is itself an NDI, a combination of grandfathered dietary ingredients is not, even if that combination has not been used in a dietary supplement before.
- *Identity information to include in an NDI notification*—We revised several questions and answers in section VI.A in consideration of comments regarding chemical and botanical information necessary to determine the identity of an NDI. We also added a new question and answer with recommendations about what chemistry information should be included in a notification for an enzyme NDI. In addition, since some of the standard references on nomenclature of plants and microorganisms have been renamed or updated since the 2011 draft guidance, we updated the citations to refer to the most recent edition.
- *Electronic submission*—We updated the question and answer in section V.A about electronic submission of NDI notifications. The updated answer states that we are accepting NDI notifications electronically and provides the Internet address for the electronic submission gateway. As before, the answer notes that firms still have the option to submit paper notifications to FDA using the procedure described in 21 CFR 190.6.
- *PDF form for NDI notifications submitted on paper*—Because our electronic submission gateway for NDI notifications is now available, we have decided not to provide a competing form for paper notifications. Therefore, we have removed "Appendix B: 75-Day Pre-Market New Dietary Ingredient Notification Form" from the draft guidance.
- *Safety information to include in an NDI notification*—We revised several questions and answers in sections VI.B and VI.C to clarify our thinking on compiling and evaluating scientific evidence about the safety of NDIs and dietary supplements that contain NDIs. In section VI.B, we clarified our thinking on the use of foreign history of use data. We also added a recommendation to consult "Principles and Methods for the Risk Assessment of Chemicals in Food," a joint publication of the World Health Organization and the Food and Agriculture Organization of the United Nations, as a useful source of information on conducting human clinical studies for NDIs and dietary supplements. In response to comments, we removed all references to FDA's "Redbook" guidance, which contains recommendations on toxicity studies and other scientific evidence needed to determine the safety of food additives. We also revised section VI.B to explain that the NDI safety standard is different from the standards for other FDA-regulated products and clarify that evidence for an NDI safety evaluation should be compiled to meet that standard. Although the revised draft

guidance no longer cites the Redbook, we continue to recommend the use of the dietary exposure assessment methodology and some toxicology tests that are also used for the evaluation of food additives because these are standard scientific methods not specific to any particular safety assessment paradigm. Finally, we added a new question at the end of section VI.C to emphasize that this draft guidance contains recommendations about safety information to include in an NDI notification, but these recommendations are not requirements.

- *Other changes*—We made clarifying changes, explanatory changes, and editorial changes throughout the document. We also updated references and links and added new references where appropriate.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This draft guidance contains proposed collections of information. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to publish a 60-day notice in the **Federal Register** soliciting public comment on each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, we intend to publish a 60-day notice on the proposed collections of information in this draft guidance in a future issue of the **Federal Register**.

This draft guidance also refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 111 have been approved under OMB control number 0901–0606, and the collections of information in § 190.6 have been approved under OMB control number 0910–0330.

III. Other Issues for Consideration

Although FDA welcomes comments on any aspect of this draft guidance, we particularly invite comment on the following:

- What processes alter the identity of an ingredient marketed prior to October 15, 1994, and thus create an NDI? We are especially interested in recommendations for clearer examples or criteria to differentiate changes in manufacturing methods and starting materials that alter the identity of the ingredient from changes that do not.
- What processes "chemically alter" an ingredient within the meaning of section 413(a)(1) of the FD&C Act, and why? Conversely, what processes do not cause chemical alteration, and why? Are there certain processes, such as tinctures, that sometimes result in chemical alteration and sometimes do not? What criteria should be used to evaluate whether an ingredient has been chemically altered? We are especially interested in receiving scientific information that shows whether a particular process actually results in chemical alteration.
- What method of compiling independent and verifiable data on the marketing of dietary ingredients before October 15, 1994, would be most effective? How should an authoritative list of "grandfathered" ingredients based on such data be developed and implemented?

As FDA considers the development of final guidance, we will review comments received on this revised version, as well as comments on the 2011 draft guidance that are still relevant.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/FoodGuidances* or *http://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the draft guidance.

V. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. International Programme on Chemical Safety, "Principles and Methods for the Risk Assessment of Chemicals in Food," *Environmental Health Criteria* 240 (2009), available at: *http://www.who.int/foodsafety/publications/chemical-food/en/.*
2. The official name of the Redbook is "Guidance for Industry and Other Stakeholders: Toxicological Principles for the Safety Assessment of Food Ingredients," available at: *http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm2006826.htm.*

Dated: August 9, 2016.

Jeremy Sharp,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2016–19306 Filed 8–11–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Health Center Program Application Forms

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than September 12, 2016.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Health Center Program Application Forms OMB No. 0915–0285—Revision.

Abstract: Health centers (those entities funded under Public Health Service Act section 330 and Health Center Program look-alikes) deliver comprehensive, high quality, cost-effective primary health care to patients regardless of their ability to pay. Health centers are an essential primary care provider for America's most vulnerable populations. Health centers provide coordinated, comprehensive, and patient-centered primary and preventive health care. Nearly 1,400 health centers operate more than 9,800 service delivery sites that provide care in every state, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and the Pacific Basin.

The Health Center Program is administered by HRSA's Bureau of Primary Health Care (BPHC). BPHC uses multiple Health Center Program-specific forms (see table below) to oversee the Health Center Program.

Need and Proposed Use of the Information: Health Center Program-specific forms are critical to Health Center Program grant and non-grant award processes and for Health Center Program oversight. The purpose of these forms is to provide HRSA staff and objective review committee panels information essential for application evaluation, funding recommendation, approval, designation, and monitoring. These forms also provide HRSA staff with information essential for ensuring compliance with Health Center Program legislative and regulatory requirements. These application forms are used by existing health centers and other organizations to apply for various grant and non-grant opportunities, renew their grant or non-grant designation, and change their scope of project.

Most of the Health Center Program-specific forms do not require any significant changes with this revision. HRSA intends to revise some of the forms to streamline and clarify data already being requested (Form 1A, 1B, 2, 3, 5A, 5B, 6A, 8, Performance Measures, Project Work Plan, Outreach and Enrollment Progress Report) and change several form names (changing Form 3A to Look-Alike Budget Information, Form 10 to Emergency Preparedness Report, and Increased Demand for Services to Expanded Services). HRSA also intends to add seven new forms. The Supplemental Information form and Summary Page will consolidate important application information that is usually found distributed throughout the application, including eligibility criteria and projected goals. These forms will require applicant confirmation that the information provided is accurate. Two of these new forms will include the Program Narrative Update, used to report progress for renewal of Health Center Program awards, and the Substance Abuse Progress Report, used to report quarterly progress for award recipients of Substance Abuse Expansion supplemental funding. Two other forms, the Health Center Controlled Networks Work Plan and Progress Report, are forms that have been used in the past (under another OMB control number) to collect application baseline data and progress metrics for grantees. An additional new form, Zika Progress Report, will collect quarterly progress on Zika-related projects.

Likely Respondents: Health Center Program award recipients and look-alikes, state and national technical assistance organizations, and other organizations seeking funding.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Form 1A: General Information Worksheet	1,700	1	1,700	1.0	1,700
Form 1B: BPHC Funding Request Summary	450	1	450	0.75	337.5
Form 1C: Documents on File	1,000	1	1,000	0.5	500
Form 2: Staffing Profile	1,700	1	1,700	1.0	1,700
Form 3: Income Analysis	1,900	1	1,900	2.5	4,750
Form 3A: Look-Alike Budget Information	100	1	100	1.0	100
Form 4: Community Characteristics	1,000	1	1,000	1.0	1,000
Form 5A: Services Provided	1,700	1	1,700	1.0	1,700
Form 5B: Service Sites	1,200	1	1,200	0.75	900
Form 5C: Other Activities/Locations	1,000	1	1,000	0.5	500
Form 6A: Current Board Member Characteristics	1,000	1	1,000	0.5	500
Form 6B: Request for Waiver of Governance Requirements	100	1	100	1.0	100
Form 8: Health Center Agreements	600	1	600	0.75	450
Form 9: Need for Assistance Worksheet	500	1	500	4.5	2,250
Form 10: Emergency Preparedness Report	1,000	1	1,000	1.0	1,000
Form 12: Organization Contacts	1,000	1	1,000	0.5	500
Clinical Performance Measures	1,000	1	1,000	3.5	3,500
Financial Performance Measures	1,000	1	1,000	1.0	1,000
Implementation Plan	900	1	900	3.0	2,700
Project Work Plan	200	1	200	5.0	1,000
Proposal Cover Page	400	1	400	1.0	400
Project Cover Page	400	1	400	1.0	400
Equipment List	400	1	400	1.0	400
Other Requirements for Sites	400	1	400	0.5	200
Funding Sources	400	1	400	0.5	200
Project Qualification Criteria	400	1	400	1.0	400
O&E Supplemental	1,200	1	1,200	1.0	1,200
O&E Progress Report	1,200	1	1,200	1.0	1,200
Checklist for Adding a New Service Delivery Site	700	1	700	1.5	1,050
Checklist for Deleting Existing Service Delivery Site	700	1	700	1.0	700

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS—Continued

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Checklist for Adding New Service	700	1	700	1.0	700
Checklist for Deleting Existing Service	700	1	700	1.0	700
Checklist for Adding a New Target Population	50	1	50	0.5	25
Expanded Services	1,400	1	1,400	1.0	1,400
Federal Object Class Categories	1,400	1	1,400	0.25	350
Supplemental Information (NEW)	2,000	1	2,000	0.5	1,000
Summary Page (NEW)	1,700	1	1,700	0.25	425
Program Narrative Update (NEW)	900	1	900	4.0	3,600
Substance Abuse Progress Report (NEW)	300	4	1,200	1.0	1,200
Health Center Controlled Networks Progress Report (NEW)	93	1	93	25	2,325
Health Center Controlled Networks Work Plan (NEW)	93	1	93	5.0	465
Zika Progress Report (NEW)	20	4	80	1.0	80
Total	34,606		35,566		44,608

Jason E. Bennett,

Director, Division of the Executive Secretariat.

[FR Doc. 2016–19301 Filed 8–11–16; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; Rapid Assessment of Zika Virus Complications (2017/01).

Date: September 12, 2016.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, Suite 920, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Dennis Hlasta, Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Blvd., Bethesda, MD 20892, (301) 451–4794, *dennis.hlasta@nih.gov.*

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; 2017–01 R25 Application Review.

Date: September 28, 2016.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, Suite 920, 6707 Democracy Boulevard, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Ruixia Zhoua, Ph.D., Scientific Review Officer, 6707 Democracy Boulevard, Democracy Two Building, Suite 957, Bethesda, MD 20892, (301) 496–473, *zhour@mail.nih.gov.*

Dated: August 8, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–19191 Filed 8–11–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

Date: September 13, 2016.

Open: 8:30 a.m. to 12:00 p.m.

Agenda: Discussion of program policies.

Place: National Institutes of Health, Building 31, 31 Center Drive, 6th Floor, C Wing, Conference Room 6, Bethesda, MD 20892.

Closed: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, 31 Center Drive, 6th Floor, C Wing, Conference Room 6, Bethesda, MD 20892.

Contact Person: Laura K. Moen, Ph.D., Director, Division of Extramural Research Activities, NIAMS/NIH, 6700 Democracy Boulevard, Suite 800, Bethesda, MD 20892, 301–451–6515, *moenl@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: August 5, 2016.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–19192 Filed 8–11–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Projects: New Modalities for the Treatment of Pain and Drug Abuse.

Date: September 8, 2016.

Time: 2:30 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Geoffrey G. Schofield, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4040–A, MSC 7850, Bethesda, MD 20892, 301–435–1235, *geoffreys@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR 16–054 Shared Instrumentation: Biomedical Imaging.

Date: September 12, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Alexandria Mark Center, 5000 Seminary Road, Alexandria, VA 22311.

Contact Person: Jan Li, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5106, Bethesda, MD 20892, 301.435.1049. *jan.li@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 8, 2016.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–19194 Filed 8–11–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Minority Health and Health Disparities; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Council on Minority Health and Health Disparities.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council on Minority Health and Health Disparities.

Date: September 12, 2016.

Closed: 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 31 Center Drive, Building 31, 6th Floor, Conference Room 10, 9000 Rockville Pike, Bethesda, MD 20892.

Date: September 13, 2016.

Open: 8:00 a.m. to 2:30 p.m.

Agenda: The agenda will include opening remarks, administrative matters, Director's Report, NIH Health Disparities update, and other business of the Council.

Place: National Institutes of Health, 31 Center Drive, Building 31, 6th Floor, Conference Room 10, 9000 Rockville Pike, Bethesda, MD 20892.

Contact Person: Dr. Joyce Hunter, Executive Secretary, National Institutes of Health, National Institute on Minority Health and Heath Disparities, 6707 Democracy Blvd., Suite 800, Bethesda, MD 20892, (301) 402–1366, *hunterj@nih.gov.*

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxis, hotel, and airport shuttles, will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Dated: August 8, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–19190 Filed 8–11–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Human Genome Research Institute Special Emphasis Panel; Gabriella Miller Kids First Review.

Date: September 8–9, 2016.

Time: 7:00 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, Room Chevy Chase 1, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Barbara J. Thomas, Ph.D., Scientific Review Officer, Scientific Review Branch, National Human Genome Research Institute, National Institutes of Health, 5635 Fishers Lane, Ste. 4076, MSC 9306, Bethesda, MD 20892–9306, 301–402–0838, *barbara.thomas@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: August 5, 2016.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–19193 Filed 8–11–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

[Docket No. SAMHSA–2016–0002]

Request for Comment on Report Entitled: Advancing the Care of Pregnant and Parenting Women With Opioid Use Disorder and Their Infants: A Foundation for Clinical Guidance

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services (HHS).

ACTION: Request for comment.

SUMMARY: Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment, in the Department of Health and Human Services (HHS) announces the opening of a docket to obtain public comment on a report entitled: Advancing the Care of Pregnant and Parenting Women with Opioid Use Disorder and their Infants: A Foundation for Clinical Guidance. The report is available at: *http://www.regulations.gov/docket?D=SAMHSA-2016-0002.*

This report describes the formal process agreed on and followed under the guidance of the federal steering committee (FSC). It explains the RAND Corporation (RAND)/University of California Los Angeles (UCLA) Appropriateness Method (RAM), justifies its adoption, and reports the outcomes of its application that will form the basis for the development of clinical guidance. This report will serve as the foundation for the development of clinical guidance to be used by providers caring for women with opioid use disorder and their infants.

DATES: *Comment Close Date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. no later than 30 days after date of publication in the **Federal Register**.

ADDRESSES: You may submit comments identified by Docket No. [SAMHSA–2016–0002] by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Electronically:* You may submit electronic comments to *samhsa.ppdaoram@samhsa.hhs.gov.*
- *By regular mail:* You may mail written comments to the following address ONLY: Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment, Division of Pharmacologic Therapies, 5600 Fishers Lane, 13E24, Rockville, MD 20852 Attn: Docket No. [SAMHSA–2016–0002]. Please allow sufficient time for mailed comments to be received before the close of the comment period.
- *By express or overnight mail:* You may send written comments to the following address ONLY: Substance Abuse and Mental Health Services Administration, Attention: DPT **Federal Register** Representative, Division of Pharmacologic Therapies, 5600 Fishers Lane, 13E24, Rockville, MD 20852 Attn: Docket No. [SAMHSA–2016–0002].
- *By hand or courier:* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following address prior to the close of the comment period: For delivery in Rockville, MD: Substance Abuse and Mental Health Services Administration, Attention: DPT **Federal Register** Representative, Division of Pharmacologic Therapies, 5600 Fishers Lane, 13E24, Rockville, MD 20852. To deliver your comments to the Rockville address, call telephone number (240) 276–2700 in advance to schedule your delivery with one of our staff members.

Instructions: To avoid duplication, please submit only one copy of your comments by only one method. All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. For access to the report or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Melinda Campopiano, MD, Medical Officer, Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment, Division of Pharmacologic Therapies, 5600 Fishers Lane, 13E24, Rockville, MD 20852, Email: *samhsa.ppdaoram@samhsa.hhs.gov.*

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. Comments received by the deadline will be available for public inspection at the Substance Abuse and Mental Health Services Administration, Division of Pharmacologic Therapies, 5600 Fishers Lane, 13E24, Rockville, MD 20852, Monday through Friday of each week from 8:30 a.m. to 4:00 p.m. To schedule an appointment to view public comments, phone (240) 276–2700.

Background: SAMHSA led a federal steering committee in overseeing the application of the RAND/UCLA Appropriateness Method (RAM) to the available evidence concerning the optimal management of opioid use disorder for women who are pregnant or parenting and the management of their infants. After completion of the literature review, generation of the indications, and the expert panel RAM rating process—all described in this report—this report was generated for the purpose of producing a clinical guide that will be written to facilitate optimal management of pregnant and parenting women with opioid use disorder and their infants across disciplines and treatment settings. The guide will have a dual purpose: first, to serve as a tool that will increase provider willingness and confidence to manage pregnant and parenting women with opioid use disorder and their infants; and second to help assure the care provided this population optimizes the outcomes for both mother and infant.

The purpose of this effort is to produce a patient-centered guide to be used in a range of clinical settings. SAMHSA plans to organize the results described in this report around clinical scenarios and interventions consistent with the range of ways that women with opioid use disorder may access substance use treatment or maternity care. The guide will provide options for clinical interventions that recognize the complexities of patients' lives. The guide will also include discussion of any conflicting evidence and clinician, treatment or patient characteristics that directly influence the appropriateness or effectiveness of a given clinical intervention. The paucity of the evidence to support specific interventions will be addressed in the guide. As such, the guide will present options based on current clinical practice, paired with the risks and benefits of each option as currently understood.

Public comment is sought in two general areas: The outcomes of the RAM process and the strategy to translate these findings into a clinical guide. Relevant public comment will inform the development and final appearance of the guide. Members of the expert panel, FSC, and a variety of professional societies will be asked to provide input into the guide outline and drafting of the guide which will then be subject to a formal federal clearance process including scientific review.

Supporting and Related Material in the Docket: The report contains the materials to help inform public comment. The appendices include listings of participants, more detailed information about the literature search, citations of primary references and data tables that were used by SAMHSA to develop the findings in the report. The information provided includes:

(1) The REPORT

(2) Supporting appendices: Appendix A: RAM Process Participants; Appendix B: Literature Review Methods; Appendix C: RAM Reference List and Appendices D–E7: Rated Indications

Charles LoDico,

Chemist, SAMHSA/CSAP.

[FR Doc. 2016–19187 Filed 8–11–16; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer at 240–276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: SAMHSA Disaster Technical Assistance Center Disaster Behavioral Health Needs Assessment and Customer Satisfaction Surveys (OMB No. 0930–0325)—Revision

The Substance Abuse and Mental Health Services Administration (SAMHSA) is requesting approval for a revision to the data collection associated with the SAMHSA Disaster Technical Assistance Center (DTAC) Disaster Behavioral Health Needs Assessment and Customer Satisfaction Surveys (OMB No. 0930–0325), which expire on May 31, 2017. Specifically, SAMHSA DTAC plans to consolidate the Needs Assessment Survey and Customer Satisfaction Surveys into a single instrument. The new revised instrument, entitled SAMHSA DTAC Customer Feedback Survey (CFS), under this effort will also include a change in administration to make it appropriate for a single, streamlined survey.

The proposed data collection effort will provide feedback on the overall effectiveness of SAMHSA DTAC's services, ongoing needs at the national level, and areas that require enhanced technical assistance (TA) services.

SAMHSA DTAC will be responsible for administering the data collection instrument and analyzing the data. SAMHSA DTAC will use data from the instrument to inform current and future TA activities and to ensure these activities continue to align with state and local needs.

A three-year clearance is being requested. The SAMHSA DTAC CFS is designed to allow the agency to collect feedback on the overall effectiveness of the services provided by SAMHSA DTAC, as well as ongoing data regarding disaster behavioral health (mental health and substance use-related) needs at the national level and areas that require enhanced training and technical assistance (TA) services. This is the information that was previously collected as part of the SAMHSA DTAC Needs Assessment Survey (NAS) and Customer Satisfaction Survey (CSS). Data from this effort will continue to be used to improve services to jurisdictions, which will lead to (1) better integration of disaster behavioral health (DBH) needs with all-hazards disaster preparedness and response, and (2) improved outcomes at the state, territory, tribal, and local levels with less burden on participants. The new Customer Feedback Survey integrates and consolidates questions from the previously utilized NAS and CSS, which will reduce burden associated with the number of instruments and survey questions. SAMHSA DTAC will continue to be responsible for survey administration and analysis of the data collected, which SAMHSA will use to inform current and future training and TA activities. Table 1 shows the estimated burden associated with CFS data collection activities and the associated costs. It is anticipated that the survey will be administered once each year.

Participation in the Customer Feedback Survey will be solicited from all 50 states, the U.S. territories, and the District of Columbia. The survey will be administered to individuals who have requested TA within the six months prior to administration and those who are subscribed to DTAC's e-communications, *SAMHSA DTAC Bulletin,* or *The Dialogue,* at the time of administration. Internet-based technology will be used to collect data via web-based survey for data entry and management.

TABLE 1—ANNUALIZED ESTIMATE OF RESPONDENT BURDEN

Type of respondent	Instrument	Number of respondents	Number of responses	Total number of responses	Hours per response	Total burden hours
TA requestor, e-communications recipient, colleague of previous requestor.	DTAC Customer Feedback Survey.	200	1	200	0.5	100

Send comments to Summer King, SAMHSA Reports Clearance Officer, 5600 Fishers Lane, 15E57–B, Rockville, MD 20857 *OR* email a copy to *summer.king@samhsa.hhs.gov.* Written comments should be received by October 11, 2016.

Summer King,

Statistician.

[FR Doc. 2016–19206 Filed 8–11–16; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: Interviews With Grantees Integrating Behavioral Health Treatment, Prevention, and HIV Medical Care Services (OMB NO. 0930–0336)—Reinstatement

SAMHSA is requesting Office of Management and Budget (OMB) approval to conduct in-person Site Visit Interviews with Minority AIDS Initiative—Continuum of Care (MAI–CoC) Grantees Integrating Behavioral Health Treatment, Prevention, and HIV Medical Care Services. This reinstatement request utilizes revised versions of the site visit interview guide approved under the Minority AIDS Initiative—Targeted Capacity Expansion (MAI–TCE) Grantees Integrating HIV Primary Care, Substance Abuse, and Behavioral Health Services (OMB NO. 0930–0336). The two rounds of interviews (baseline and follow-up) target the collection of programmatic-level data (*e.g.,* community context, organizational structure, and staffing and staff development, services and service model, outreach, referral and enrollment into services, services/care coordination and integration and funding for integrated services and program successes and challenges) through one-on-one and group interviews with grantees who are part of the MAI–CoC program.

The goal of the MAI–CoC project is to integrate behavioral health treatment, prevention, and HIV and Hepatitis medical care services for racial/ethnic minority populations at high risk for behavioral health disorders who are also at high risk for or living with HIV and Hepatitis. The program also supports other priority populations including men who have sex with men (MSM) and bisexual men, transgender persons, and people with substance use disorder. The program is primarily intended for substance use disorder treatment and community mental health providers to provide coordinated and integrated services through the collocation and/or integration of behavioral health treatment and HIV and Hepatitis medical care. Interviews conducted with MAI–CoC grantees during the two rounds of site visits are an integral part of evaluation efforts to: (1) Assess the impact of the SAMHSA-funded HIV and Hepatitis programs in: Reducing behavioral health disorders and HIV and Hepatitis infections; increasing access to substance use disorder and mental disorder treatment and care; improving behavioral and mental health outcomes; and reducing HIV and Hepatitis-related disparities; (2) Describe the different integrated behavioral health and medical program models; and (3) Determine which program types or models are most effective in improving behavioral health and clinical outcomes.

Over the four-year project, SAMHSA will conduct two rounds of these in-person site visits (baseline and follow-up) with each of the 34 MAI–CoC program grantees.

SAMHSA will conduct one-on-one and group interviews with MAI–CoC grantee staff who will provide information on their program's integration of HIV and Hepatitis prevention, medical care, and primary care into behavioral health services. While participating in the evaluation is a condition of the grantees' funding, participating in the interview process is voluntary. The instruments are designed to collect information about: (1) The development and changes in MAI–CoC program operations, staffing, training and programming; (2) the grantee organization, the MAI–CoC program and its structure, the community context surrounding program efforts, and changes that result from MAI–CoC activities; and, (3) the changes in the number or nature of partnerships and collaborations both internal and external to the MAI–CoC program grantee.

Below is the table of the estimated total burden hours:

Data collection tool	Number of respondents	Number of responses per respondent	Total number responses	Hour per response	Total burden hours
Initial Site Visit Interview Guide	306	1	306	2	612
Follow-up Site Visit Interview Guide	306	1	306	1	306
Total	306		612		918

Written comments and recommendations concerning the proposed information collection should be sent by September 12, 2016 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@omb.eop.gov.* Although commenters are encouraged to send their comments via email, commenters may also fax their comments to: 202–395–7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

Summer King,

Statistician.

[FR Doc. 2016–19214 Filed 8–11–16; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Quarterly IRS Interest Rates Used In Calculating Interest on Overdue Accounts and Refunds on Customs Duties

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: General notice.

SUMMARY: This notice advises the public that the quarterly Internal Revenue Service interest rates used to calculate interest on overdue accounts (underpayments) and refunds (overpayments) of customs duties will remain the same from the previous quarter. For the calendar quarter beginning July 1, 2016, the interest rates for overpayments will be 3 percent for corporations and 4 percent for non-corporations, and the interest rate for underpayments will be 4 percent for both corporations and non-corporations. This notice is published for the convenience of the importing public and U.S. Customs and Border Protection personnel.

DATES: *Effective Date:* July 1, 2016.

FOR FURTHER INFORMATION CONTACT: Kara N. Welty, Revenue Division, Collection and Refunds Branch, 6650 Telecom Drive, Suite #100, Indianapolis, Indiana 46278; telephone (317) 614–4614.

SUPPLEMENTARY INFORMATION:

Background

Pursuant to 19 U.S.C. 1505 and Treasury Decision 85–93, published in the **Federal Register** on May 29, 1985 (50 FR 21832), the interest rate paid on applicable overpayments or underpayments of customs duties must be in accordance with the Internal Revenue Code rate established under 26 U.S.C. 6621 and 6622. Section 6621 provides different interest rates applicable to overpayments: One for corporations and one for non-corporations.

The interest rates are based on the Federal short-term rate and determined by the Internal Revenue Service (IRS) on behalf of the Secretary of the Treasury on a quarterly basis. The rates effective for a quarter are determined during the first-month period of the previous quarter.

In Revenue Ruling 2016–12, the IRS determined the rates of interest for the calendar quarter beginning July 1, 2016, and ending on September 30, 2016. The interest rate paid to the Treasury for underpayments will be the Federal short-term rate (1%) plus three percentage points (3%) for a total of four percent (4%) for both corporations and non-corporations. For corporate overpayments, the rate is the Federal short-term rate (1%) plus two percentage points (2%) for a total of three percent (3%). For overpayments made by non-corporations, the rate is the Federal short-term rate (1%) plus three percentage points (3%) for a total of four percent (4%). These interest rates are subject to change for the calendar quarter beginning October 1, 2016, and ending December 31, 2016.

For the convenience of the importing public and U.S. Customs and Border Protection personnel the following list of IRS interest rates used, covering the period from before July of 1974 to date, to calculate interest on overdue accounts and refunds of customs duties, is published in summary format.

Beginning date	Ending date	Under-payments (percent)	Over-payments (percent)	Corporate overpayments (Eff. 1–1–99) (percent)
070174	063075	6	6	
070175	013176	9	9	
020176	013178	7	7	
020178	013180	6	6	
020180	013182	12	12	
020182	123182	20	20	
010183	063083	16	16	
070183	123184	11	11	
010185	063085	13	13	
070185	123185	11	11	
010186	063086	10	10	
070186	123186	9	9	
010187	093087	9	8	
100187	123187	10	9	
010188	033188	11	10	
040188	093088	10	9	
100188	033189	11	10	
040189	093089	12	11	
100189	033191	11	10	
040191	123191	10	9	
010192	033192	9	8	
040192	093092	8	7	
100192	063094	7	6	
070194	093094	8	7	
100194	033195	9	8	
040195	063095	10	9	
070195	033196	9	8	

Beginning date	Ending date	Under-payments (percent)	Over-payments (percent)	Corporate overpayments (Eff. 1–1–99) (percent)
040196	063096	8	7	
070196	033198	9	8	
040198	123198	8	7	
010199	033199	7	7	6
040199	033100	8	8	7
040100	033101	9	9	8
040101	063001	8	8	7
070101	123101	7	7	6
010102	123102	6	6	5
010103	093003	5	5	4
100103	033104	4	4	3
040104	063004	5	5	4
070104	093004	4	4	3
100104	033105	5	5	4
040105	093005	6	6	5
100105	063006	7	7	6
070106	123107	8	8	7
010108	033108	7	7	6
040108	063008	6	6	5
070108	093008	5	5	4
100108	123108	6	6	5
010109	033109	5	5	4
040109	123110	4	4	3
010111	033111	3	3	2
040111	093011	4	4	3
100111	033116	3	3	2
040116	093016	4	4	3

Dated: August 8, 2016.

R. Gil Kerlikowske,

Commissioner.

[FR Doc. 2016–19167 Filed 8–11–16; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

National Customs Automation Program (NCAP) Test Concerning Electronic Filing of Protests in the Automated Commercial Environment (ACE)

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: General notice.

SUMMARY: This document announces U.S. Customs and Border Protection's (CBP's) plan to conduct a National Customs Automation Program (NCAP) test to assess new functionalities related to the electronic filing and processing of protests and new notification procedures for protests filed electronically in the Automated Commercial Environment (ACE). During the test, participants will be able to submit additional arguments and supporting information electronically, with their electronic protest in ACE. In addition, participants will be able to submit requests for further review, requests for accelerated disposition, requests to set aside denial of further review, and requests to void denial of a protest electronically in ACE. This notice also announces the testing of electronic protest status notifications from CBP. The test will be known as the ACE Protest Test.

DATES: The ACE Protest Test will commence on August 29, 2016, and will continue until concluded by a notice published in the **Federal Register**. Comments concerning this notice and any aspect of the test may be submitted at any time during the test to the address set forth below.

ADDRESSES: Comments concerning this notice and any aspect of the ACE Protest Test may be submitted at any time during the testing period via email to Josephine Baiamonte, ACE Business Office (ABO), Office of Trade at *josephine.baiamonte@cbp.dhs.gov.* In the subject line of your email, please indicate, "Comment on ACE Protest Test FRN."

FOR FURTHER INFORMATION CONTACT: For technical questions related to the application or requests for an ACE Portal Account, including ACE Protest Filer Accounts, contact the ACE Account Service Desk by calling 1–866–530–4172, selecting option 1, then option 2, or by emailing *ACE.Support@cbp.dhs.gov* for assistance.

SUPPLEMENTARY INFORMATION:

I. The National Customs Automation Program

The National Customs Automation Program (NCAP) was established by Subtitle B of Title VI—Customs Modernization in the North American Free Trade Agreement Implementation Act (Customs Modernization Act) (Pub. L. 103–182, 107 Stat. 2057, 2170, December 8, 1993) (19 U.S.C. 1411). Through NCAP, the thrust of customs modernization was on trade compliance and the development of the Automated Commercial Environment (ACE), the planned successor to the Automated Commercial System (ACS). ACE is an automated and electronic system for commercial trade processing which is intended to streamline business processes, facilitate growth in trade, ensure cargo security, and foster participation in global commerce, while ensuring compliance with U.S. laws and regulations and reducing costs for U.S. Customs and Border Protection (CBP) and all of its communities of interest. The ability to meet these objectives depends on successfully modernizing CBP's business functions and the information technology that supports those functions. CBP's modernization efforts are accomplished through phased releases of ACE component functionality designed to replace specific legacy ACS functions and add new functionality.

Sections 514 and 515 of the Tariff Act of 1930, as amended (19 U.S.C. 1514 and 1515), provide procedures for protesting certain decisions made by CBP. Section 645 of the Customs Modernization Act amended section 514(c)(1) of the Tariff Act of 1930 (19 U.S.C. 1514(c)(1)) to permit the transmission of such protests to CBP electronically. The CBP regulations governing protests are found in part 174 of Title 19 of the Code of Federal Regulations (19 CFR part 174).

II. Authorization for the ACE Protest Test

The Customs Modernization Act authorizes the Commissioner of CBP to conduct limited test programs or procedures designed to evaluate planned components of the NCAP. The ACE Protest Test is authorized pursuant to 19 CFR 101.9(b) which provides for the testing of NCAP programs or procedures. *See* Treasury Decision (T.D.) 95–21.

III. Electronic Protest Program

A. ACS Protest Filing

The electronic filing and status of protests is a planned component of the NCAP, authorized by section 411 of the Tariff Act of 1930, as amended by section 631 of the Customs Modernization Act. *See* 19 U.S.C. 1411(a)(2)(A). The U.S. Customs Service, the legacy agency of CBP, previously tested and deployed electronic protest filing using the Automated Broker Interface (ABI) to transmit a protest to ACS. *See, e.g.,* 65 FR 39224 (June 23, 2000).

On January 14, 2011, CBP published a Final Rule in the **Federal Register** (76 FR 2573) making technical corrections to the protest regulations in 19 CFR part 174 and related provisions in Title 19 of the CFR. The rule amended section 174.12(b) to conform to section 514(c)(1) of the Tariff Act of 1930, as modified by the Customs Modernization Act, allowing a protest to be transmitted electronically to the electronic data interchange system authorized by CBP for that purpose.

B. ACE Protest

CBP has developed the ACE Protest Module to replace electronic protest filing in ACS. The ACE Protest Module is an internet-based processing module, which allows any person with a Protest Filer Account in the ACE Portal to file a protest and supporting documentation electronically, monitor the status of the filer's electronic protest, and receive CBP notifications and messages regarding the protest. CBP has modified the ACE Portal Account Test to establish the Protest Filer Account. *See* 81 FR 52453 (August 8, 2016). Parties wishing to file an electronic protest will need to establish and maintain an ACE Portal Account, as specified in that notice.

In addition, on July 28, 2016, CBP published a notice in the **Federal Register** announcing that the ACE Protest Module will be the sole electronic method authorized by the Commissioner of CBP for filing electronic protests. *See* 81 FR 49685 (July 28, 2016). That notice also announced that CBP will no longer accept protests filed through ABI to ACS. Upon the effective date of that notice, ACE will replace ACS as the authorized electronic data interchange system for filing protests electronically. Pursuant to 19 CFR 174.12(b), protest filers are authorized to transmit their protest electronically to ACE.

IV. Test Participation Criteria

CBP is conducting a test of the ACE Protest Module, to assess new functionalities related to the electronic filing and processing of protests and new notification procedures for protests filed electronically in ACE. Any party who wishes to participate in this test may do so as long as it has a Protest Filer Account. Participation in this test is not confidential information and CBP may disclose the name(s) of participants. When a participant in the ACE Protest Test files a protest in ACE, the entire protest process will be fully automated and must be completed in ACE, with the exception of a request for accelerated disposition, which must be sent by registered or certified mail as required under 19 U.S.C. 1515(b). Once a test participant files a protest as part of this test, the protest filer agrees to the test procedures below for all subsequent actions regarding the protest. For test participants, CBP will waive certain regulations pertaining to protest filing, as described below. Except where otherwise specified by this notice, the CBP regulations concerning the filing of a protest remain the same.

A. Power of Attorney and Certification

The regulations governing the ability to file a protest on behalf of another person are codified at 19 CFR 174.3. For participants in the ACE Protest Test, rather than submitting a power of attorney, the protest filer will be required to check a box affirming the following statement:

> I certify that I am authorized to file this protest, that such authority has been granted by a duly and properly executed Power of Attorney where one is required, that all the information, statements and assertions herein are true and correct to the best of my knowledge and belief, and that this protest complies with all applicable regulations.

A protest filer will not be able to submit a protest electronically unless the box next to the certification statement is checked. The protest filer must maintain a copy of the power of attorney to provide to CBP upon request.

B. Identity of Filer

The CBP regulations require that a protest include the name of the person filing the protest, or his agent or attorney. *See* 19 CFR 174.12(c). Participants in the ACE Protest Test should identify the person filing the protest through the Protest Filer Account. Information identifying the filer of the protest, as required by section 174.12(c), will be collected at the time the protest filer establishes an account. In addition, the Protest Filer will be required to enter the capacity in which it is filing, by selecting a "filer type" (*e.g.,* attorney, broker, importer/consignee, or surety).

C. Place of Filing

The CBP regulations require a protest to be filed with the port director whose decision is being protested. *See* 19 CFR 174.12(d). Delegation Order Number 14–004, effective on September 11, 2014, delegates concurrent trade authority to the port directors and the directors of the Centers of Excellence & Expertise (CEE). As a result, a protest may be submitted to either the port director or the director of the filer's assigned CEE. For participants in the ACE Protest Test, electronic protests will be filed in the ACE Protest Module instead. Protests filed electronically through the module will be routed to the CBP port, CEE, or other office responsible for the decision that is the subject of the protest.

D. Date of Filing

The CBP regulations state that the date of filing of a protest is the date on which the protest is received by the Customs officer with whom it is required to be filed. *See* 19 CFR 174.12(f). For electronic filings, the date of filing for claims or information (including a protest, protest amendment, request to set aside denial of further review, and request to void denial of a protest) will be the date on which the protest is received by the ACE Protest Module. The date of filing in the ACE Protest Module will be determined based on midnight Eastern Standard Time (EST). This means that, to be considered timely, an electronic filing in the ACE Protest Module must be received by 11:59 p.m. (EST) on the final day of the filing period. The protest filer and any other designated parties will receive an electronic message confirming receipt of a protest filing in ACE.

E. Amendment of Protests

The Protest Filer may amend an electronic protest according to the requirements set forth in section 174.14. As required under 19 CFR 174.14(b), when a Protest Filer files a protest electronically, any amendment to such protest must be made electronically through the ACE Protest Module. As a result, for participants in the ACE Protest Test, the place of filing of an amendment to a protest filed in ACE will be the ACE Protest Module, rather than the port director with whom the protest was filed. *See* 19 CFR 174.14(e). The date of filing of an amendment to an ACE Protest will be the date on which the protest amendment is received by the ACE Protest Module. The date of filing in the ACE Protest Module will be determined by the time of receipt of the amendment in ACE based on midnight Eastern Standard Time. The Protest Filer and any other designated parties will receive an electronic message confirming receipt of an amendment made to an electronic protest.

F. Accelerated Disposition

Under 19 U.S.C. 1515(b), a request for accelerated disposition must be sent by registered or certified mail. If the Protest Filer intends to request accelerated disposition for a protest, the request must be sent by registered or certified mail to the port director or other CBP officer whose decision is protested. *See* 19 CFR 174.12(d) and 174.22(a). Test participants are also required to check a box in the ACE Protest Module indicating a request was properly mailed. When making a request for accelerated disposition the Protest Filer must check a box affirming that the Protest Filer has filed the request for accelerated disposition by registered or certified mail:

> I certify that I have sent a request for Accelerated Disposition by Certified or Registered United States Mail, and I understand that by requesting accelerated disposition this protest will be deemed denied within 30 days of the request if it is not decided by CBP before the end of the 30 day period, and that any lawsuit filed in the United States Court of International Trade contesting the deemed denial of this protest is barred unless commenced within 180 days of the date of the deemed denial.

The date of the request for accelerated disposition will be based on the date of the mailing. The Protest Filer may electronically withdraw a request for accelerated disposition of a protest filed through the ACE Protest Module any time prior to the 30 days after the date of the request or the CBP decision on the protest, whichever comes first.

G. Further Review

In lieu of filing an application for further review (AFR) on Customs Form 19, pursuant to 19 CFR 174.25, test participants may submit an AFR concurrently with the protest in the ACE Protest Module. When a protest is filed through the ACE Protest Module, the Protest Filer must use the module to submit the AFR. When a Protest Filer applies for further review, the filer must check a box to answer "yes" or "no" to the following questions:

> Have you made prior request of a port director for a further review of the same claim with respect to the same or substantially similar merchandise?
>
> Have you received a final adverse decision from the U.S. Court of International Trade on the same claim with respect to the same category of merchandise or do you have an action involving such a claim pending before the U.S. Court of International Trade?
>
> Have you previously received an adverse administrative decision from the Commissioner of CBP or his designee or have you presently pending an application for an administrative decision on the same claim with respect to the same category of merchandise?

The ACE Protest Module will not accept a protest with an AFR unless the Protest Filer answers these three questions and provides a written justification. The written justification must be entered in the text box provided or uploaded separately.

H. Additional Arguments

A reviewing officer may consider alternative claims and additional grounds or arguments submitted by the protesting party. *See* 19 CFR 174.28. For purposes of the ACE Protest Test, participants may use the ACE Protest Module to submit alternative claims and additional grounds or arguments any time prior to the disposition of the protest. When a protest is filed through the ACE Protest Module, the Protest Filer must use the module to submit additional arguments unless such information is incapable of electronic submission, *e.g.*, samples of imported merchandise.

I. Submission of Additional Information and Protest Withdrawal

When a protest is filed through the ACE Protest Module, the Protest Filer must use the module to submit additional information requested by CBP unless such information is incapable of electronic submission, *e.g.*, samples of imported merchandise. Any request to withdraw a protest submitted through the ACE Protest Module must be submitted electronically through the module.

J. Request To Set Aside Denial of Further Review

A Protest Filer seeking to file a request to set aside CBP's denial of further review under 19 U.S.C. 1515(c) must use the ACE Protest Module when the underlying protest was filed through the ACE Protest Module. A request will be considered filed with the appropriate CBP officer if it is filed in the ACE Protest Module within 60 days after the date of the protest denial. As noted above, the date of filing in the ACE Protest Module will be determined by the time of receipt of the request for setting aside of the denial of further review in ACE based on midnight Eastern Standard Time. If CBP fails to act on the request to set aside the denial of further review within 60 days from the time of filing, the request will be considered denied and the Protest Filer will receive a courtesy electronic notification.

K. Request To Void Denial of a Protest

A Protest Filer seeking to file a request to void the denial of a protest under 19 U.S.C. 1515(d) must use the ACE Protest Module when the underlying protest was filed through the ACE Protest Module. A request will be considered filed with the appropriate CBP office if it is filed in the ACE Protest Module within 90 days after the date of the protest denial. The date of filing of a request will be the date on which the request is received by the ACE Protest Module. As noted above, the date of filing in the ACE Protest Module will be determined by the time of receipt of the request in ACE based on midnight Eastern Standard Time.

L. Messaging

ACE will generate and send automated messages to notify the Protest Filer and any other designated parties of changes in the status of the protest and decisions made by CBP regarding the protest. These messages will advise the parties when CBP has received the: Protest; request for accelerated disposition; additional arguments; application for further review; protest amendment; request to set aside denial of further review; request to withdraw a protest; or request to void the denial of a protest. In addition, rather than mailing a notice of denial of the protest pursuant to 19 CFR 174.30, for protests filed electronically, ACE will notify designated parties of actions taken by CBP electronically, including CBP's decision to suspend, grant, or deny a protest.

V. Comments

All interested parties are invited to comment on any aspect of this ACE Protest Test for the duration of the test. CBP requests comments and feedback on all aspects of this test in order to determine whether to modify, alter, expand, limit, continue, end, or fully implement this test.

VII. Development of ACE Prototypes

A chronological listing of **Federal Register** publications detailing ACE test developments is set forth below.

- ACE Portal Accounts and Subsequent Revision Notices: 67 FR 21800 (May 1, 2002); 69 FR 5360 and 69 FR 5362 (February 4, 2004); 69 FR 54302 (September 8, 2004); 70 FR 5199 (February 1, 2005).
- ACE System of Records Notice: 71 FR 3109 (January 19, 2006).
- Terms/Conditions for Access to the ACE Portal and Subsequent Revisions: 72 FR 27632 (May 16, 2007); 73 FR 38464 (July 7, 2008).
- ACE Non-Portal Accounts and Related Notice: 70 FR 61466 (October 24, 2005); 71 FR 15756 (March 29, 2006).
- ACE Entry Summary, Accounts and Revenue (ESAR I) Capabilities: 72 FR 59105 (October 18, 2007).
- ACE Entry Summary, Accounts and Revenue (ESAR II) Capabilities: 73 FR 50337 (August 26, 2008); 74 FR 9826 (March 6, 2009).
- ACE Entry Summary, Accounts and Revenue (ESAR III) Capabilities: 74 FR 69129 (December 30, 2009).
- ACE Entry Summary, Accounts and Revenue (ESAR IV) Capabilities: 76 FR 37136 (June 24, 2011).
- Post-Entry Amendment (PEA) Processing Test: 76 FR 37136 (June 24, 2011).
- ACE Announcement of a New Start Date for the National Customs Automation Program Test of Automated Manifest Capabilities for Ocean and Rail Carriers: 76 FR 42721 (July 19, 2011).
- ACE Simplified Entry: 76 FR 69755 (November 9, 2011).
- National Customs Automation Program (NCAP) Tests Concerning Automated Commercial Environment (ACE) Document Image System (DIS): 77 FR 20835 (April 6, 2012).
- National Customs Automation Program (NCAP) Tests Concerning Automated Commercial Environment (ACE) Simplified Entry: Modification of Participant Selection Criteria and Application Process: 77 FR 48527 (August 14, 2012).
- Modification of NCAP Test Regarding Reconciliation for Filing Certain Post-Importation Preferential Tariff Treatment Claims under Certain FTAs: 78 FR 27984 (May 13, 2013).
- Modification of Two National Customs Automation Program (NCAP) Tests Concerning Automated Commercial Environment (ACE) Document Image System (DIS) and Simplified Entry (SE): 78 FR 44142 (July 23, 2013).
- Modification of Two National Customs Automation Program (NCAP) Tests Concerning Automated Commercial Environment (ACE) Document Image System (DIS) and Simplified Entry (SE); Correction: 78 FR 53466 (August 29, 2013).
- Modification of NCAP Test Concerning Automated Commercial Environment (ACE) Cargo Release (formerly known as Simplified Entry): 78 FR 66039 (November 4, 2013).
- Post-Summary Corrections to Entry Summaries Filed in ACE Pursuant to the ESAR IV Test: Modifications and Clarifications: 78 FR 69434 (November 19, 2013).
- National Customs Automation Program (NCAP) Test Concerning the Submission of Certain Data Required by the Environmental Protection Agency and the Food Safety and Inspection Service Using the Partner Government Agency Message Set Through the Automated Commercial Environment (ACE): 78 FR 75931 (December 13, 2013).
- Modification of National Customs Automation Program (NCAP) Test Concerning Automated Commercial Environment (ACE) Cargo Release for Ocean and Rail Carriers: 79 FR 6210 (February 3, 2014).
- Modification of National Customs Automation Program (NCAP) Test Concerning Automated Commercial Environment (ACE) Cargo Release to Allow Importers and Brokers to Certify From ACE Entry Summary: 79 FR 24744 (May 1, 2014).
- Modification of National Customs Automation Program (NCAP) Test Concerning Automated Commercial Environment (ACE) Cargo Release for Truck Carriers: 79 FR 25142 (May 2, 2014).
- Modification of National Customs Automation Program (NCAP) Test Concerning Automated Commercial Environment (ACE) Document Image System: 79 FR 36083 (June 25, 2014).
- Announcement of eBond Test: 79 FR 70881 (November 28, 2014).
- eBond Test Modifications and Clarifications: Continuous Bond Executed Prior to or Outside the eBond Test May Be Converted to an eBond by the Surety and Principal, Termination of an eBond by Filing Identification Number, and Email Address Correction: 80 FR 899 (January 7, 2015).
- Modification of National Customs Automation Program (NCAP) Test Concerning Automated Commercial Environment (ACE) Document Image System Relating to Animal and Plant Health Inspection Service (APHIS) Document Submissions: 80 FR 5126 (January 30, 2015).
- Modification of National Customs Automation Program (NCAP) Test Concerning the use of Partner Government Agency Message Set through the Automated Commercial Environment (ACE) for the Submission of Certain Data Required by the Environmental Protection Agency (EPA): 80 FR 6098 (February 4, 2015).
- Announcement of Modification of ACE Cargo Release Test to Permit the Combined Filing of Cargo Release and Importer Security Filing (ISF) Data: 80 FR 7487 (February 10, 2015).
- Modification of NCAP Test Concerning ACE Cargo Release for Type 03 Entries and Advanced Capabilities for Truck Carriers: 80 FR 16414 (March 27, 2015).
- Automated Commercial Environment (ACE) Export Manifest for Air Cargo Test: 80 FR 39790 (July 10, 2015).
- National Customs Automation Program (NCAP) Concerning Remote Location Filing Entry Procedures in the Automated Commercial Environment (ACE) and the Use of the Document Image System for the Submission of Invoices and the Use of eBonds for the Transmission of Single Transaction Bonds: 80 FR 40079 (July 13, 2015).
- Modification of National Customs Automation Program (NCAP) Test Concerning the Automated Commercial Environment (ACE) Partner Government Agency (PGA) Message Set Regarding Types of Transportation Modes and Certain Data Required by the National Highway Traffic Safety Administration (NHTSA): 80 FR 47938 (August 10, 2015).
- Automated Commercial Environment (ACE) Export Manifest for Vessel Cargo Test: 80 FR 50644 (August 20, 2015).
- Modification of National Customs Automation Program (NCAP) Test Concerning the Submission of Certain

Data Required by the Food and Drug Administration (FDA) Using the Partner Government Agency Message Set through the Automated Commercial Environment (ACE): 80 FR 52051 (August 27, 2015).

- Automated Commercial Environment (ACE) Export Manifest for Rail Cargo Test: 80 FR 54305 (September 9, 2015).
- Modification of the National Customs Automation Program (NCAP) Test Concerning the Automated Commercial Environment (ACE) Document Image System (DIS) Regarding Future Updates and New Method of Submission of Accepted Documents: 80 FR 62082 (October 15, 2015).
- Modification of the National Customs Automation Program (NCAP) Test Concerning the Automated Commercial Environment (ACE) Cargo Release for Entry Type 52 and Certain Other Modes of Transportation: 80 FR 63576 (October 20, 2015).
- Modification of the National Customs Automation Program (NCAP) Test Concerning the Automated Commercial Environment (ACE) Entry Summary, Accounts and Revenue (ESAR) Test of Automated Entry Summary Types 51 and 52 and Certain Modes of Transportation: 80 FR 63815 (October 21, 2015).
- Modification of the National Customs Automation Program Test Concerning the Automated Commercial Environment Portal Account to Establish the Exporter Portal Account: 80 FR 63817 (October 21, 2015).
- Modification of National Customs Automation Program Test Concerning the Automated Commercial Environment Partner Government Agency Message Set Regarding the Toxic Substances Control Act Certification Required by the Environmental Protection Agency: 81 FR 7133 (February 10, 2016).
- Notice Announcing the Automated Commercial Environment (ACE) as the Sole CBP-Authorized Electronic Data Interchange (EDI) System for Processing Certain Electronic Entry and Entry Summary Filings: 81 FR 10264 (February 29, 2016).
- Modification of the National Customs Automation Program (NCAP) Tests Concerning the Partner Government Agency Message Set for Certain Data Required by the Environmental Protection Agency (EPA): 81 FR 13399 (March 14, 2016).
- Cessation of National Customs Automation Program (NCAP) Test Concerning the Submission of Certain Data Required by the Food and Drug Administration (FDA) Using the Partner Government Agency (PGA) Message Set Through the Automated Commercial Environment (ACE): 81 FR 18634 (March 31, 2016).
- Automated Commercial Environment (ACE); Announcement of National Customs Automation Program Test of the In-Transit Manifest Pilot Program: 81 FR 24837 (April 27, 2016).
- Announcement of National Customs Automation Program (NCAP) Test Concerning the Submission Through the Automated Commercial Environment (ACE) of Certain Import Data and Documents Required by the U.S. Fish and Wildlife Service: 81 FR 27149 (May 5, 2015).
- Notice Announcing the Automated Commercial Environment (ACE) as the Sole CBP-Authorized Electronic Data Interchange (EDI) System for Processing Certain Electronic Entry and Entry Summary Filings Accompanied by Food and Drug Administration (FDA) Data: 81 FR 30320 (May 16, 2016).
- Notice Announcing the Automated Commercial Environment (ACE) as the Sole CBP-Authorized Electronic Data Interchange (EDI) System for Processing Electronic Entry and Entry Summary Filings: 81 FR 32339 (May 23, 2016).
- Notice Announcing the Automated Commercial Environment (ACE) Protest Module as the Sole CBP-Authorized Method for Filing Electronic Protests: 81 FR 49685 (July 28, 2016).
- Modification of the National Customs Automation Program (NCAP) Test Concerning the Automated Commercial Environment (ACE) Portal Accounts to Establish the Protest Filer Account and Clarification that the Terms and Conditions for Account Access Apply to All ACE Portal Accounts: 81 FR 52453 (August 8, 2016).

Dated: August 9, 2016.

Brenda B. Smith,

Executive Assistant Commissioner, Office of Trade.

[FR Doc. 2016–19267 Filed 8–11–16; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5907–N–33]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Juanita Perry, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7266, Washington, DC 20410; telephone (202) 402–3970; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), call the toll-free Title V information line at 800–927–7588 or send an email to *title5@hud.gov* .

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration*, No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, and suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where property is described as for "off-site use only" recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to: Ms. Theresa M. Ritta, Chief Real Property Branch, the Department of Health and Human Services, Room 12–07, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, (301)–443–2265 (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 or send an email to *title5@hud.gov* for detailed instructions, or write a letter to Ann Marie Oliva at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (*e.g.*, acreage, floor plan, condition of property, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: AGRICULTURE: Ms. Debra Kerr, Department of Agriculture, OPPM, Property Management Division, Agriculture South Building, 300 7th Street SW., Washington, DC 20024, (202)–720–8873; COE: Ms. Brenda Johnson-Turner, HQUSACE/CEMP–CR, 441 G Street NW., Washington, DC 20314, (202)–761–7238; ENERGY: Mr. David Steinau, Department of Energy, Office of Asset Management (MA–50), 1000 Independence Ave. SW., Washington, DC 20585, (202)–287–1503; INTERIOR: Mr. Michael Wright, Acquisition & Property Management, Department of the Interior, 3960 N. 56th Ave. #104, Hollywood, FL. 33021; (443) 223–4639; NAVY: Mr. Steve Matteo, Department of the Navy, Asset Management Division, Naval Facilities Engineering Command, Washington Navy Yard, 1330 Patterson Ave. SW., Suite 1000, Washington, DC 20374; (202)–685–9426; (These are not toll-free numbers).

Dated: August 4, 2016.

Tonya Proctor,

Deputy Director, Office of Special Needs Assistance Programs.

TITLE V, FEDERAL SURPLUS PROPERTY PROGRAM FEDERAL REGISTER REPORT FOR 08/12/2016

Suitable/available properties

Building

Oklahoma

SWT-Eufaula Lake
Belle Starr South
102 E Bk 200 Rd.
Stigler OK 74462
Landholding Agency: COE
Property Number: 31201630007
Status: Unutilized
Directions: BSSC04
Comments: Off-site removal only; 307.98 sq. ft.; no future agency need; poor conditions; contact COE for more details.

Cowington Point
HC 61 box 238
Sallisaw OK 74955
Landholding Agency: COE
Property Number: 31201630008
Status: Unutilized
Comments: Off-site removal only; no future agency need; shelter; poor conditions; contact COE for more details.

Texas

Texoma-42477
351 Corps. Rd
Denison TX 75020
Landholding Agency: COE
Property Number: 31201630010
Status: Unutilized
Comments: Off-site removal only; no future agency need; 860.04 sq. ft.; poor conditions; contact COE for more details.

Virginia

Marine Corps Reserve Training Facility
7401 Warwick Blvd.
Newport News VA
Landholding Agency: Navy
Property Number: 77201510001
Status: Unutilized
Directions: Previously reported and published in the 01/30/2015 FR
Comments: 30,184 sq. ft.; sits on 5.02+ acres; 31+ months vacant; good to fair conditions; contact Navy for more details.

Unsuitable Properties

Building

Arkansas

Toilet-Vault, AR/LD5–42732
MKARNS Project Tar Camp Park
4600 River Rd.
Redfield AR 72132
Landholding Agency: COE
Property Number: 31201630011
Status: Unutilized
Comments: Documented deficiencies: Inundated with regular occurrence of flooding by river; clear threat to physical safety.
Reasons: Extensive deterioration

California

6 Buildings
311 Main Street
Pt. Mugu CA 93043
Landholding Agency: Navy
Property Number: 77201630007
Status: Unutilized
Directions: 557; 566; 568; 569; 570; 571
Comments: Public access denied and no alternative method to gain access without compromising national security.
Reasons: Secured Area

Naval Air Facility Substation (RPUID: 153148)
1 Administration Circle
China Lake CA 93555
Landholding Agency: Navy
Property Number: 77201630009
Status: Underutilized
Comments: Public access denied and no alternative method to gain access without compromising national security.
Reasons: Secured Area

3 Buildings
Naval Air Station North Island
Naval Base Coronado
San Diego CA 14211
Landholding Agency: Navy
Property Number: 77201630012
Status: Excess
Directions: No. C–34 (6,160 sq. ft. GPS 32.69714 N., 117.1929 W.); No. C–1 (4,211 sq. ft. GPS 32.6977 N., 117.1925 W.); Building 852 (269 sq. ft. GPS 32.68786 N., 117.22215 W.)
Comments: Public access denied and no alternative method to gain access without compromising national security; documented deficiencies: poor structural condition.
Reasons: Secured Area; Extensive deterioration

Guam

108 Single-Story Buildings
South Finegayan Family Housing Area
Finegayan GU
Landholding Agency: Navy
Property Number: 77201630008
Status: Excess
Comments: Public access denied and no alternative to gain access without compromising national security.
Reasons: Secured Area

Hawaii

Facility Number 427H
Joint Base Pearl Harbor Hickam
Honolulu HI 96860
Landholding Agency: Navy
Property Number: 77201630010
Status: Excess
Directions: Tennis Pro-Shop
Comments: Public access denied and no alternative method to gain access without compromising national security.
Reasons: Secured Area

Building 81A

Marine Corps Base
Camp Smith HI
Landholding Agency: Navy
Property Number: 77201630011
Status: Excess
Comments: Public access denied and no alternative method to gain access without compromising national security.
Reasons: Secured Area

Iowa

L80004, RTHBUN–29396
Shower Building in South Fork area
Rathbun Project; 13736 Shrike Pl.
Mystic IA 52574
Landholding Agency: COE
Property Number: 31201630003
Status: Excess
Comments: Documented deficiencies: Doors and walls rotten; clear threat to physical safety.
Reasons: Extensive deterioration

15015, RTHBUN–29330
Shower Building in Buck Creek area
21837 Marina Pl.
Moravia IA 52571
Landholding Agency: COE
Property Number: 31201630004
Status: Excess
Comments: Documented deficiencies: Doors and walls rotten; clear threat to physical safety.
Reasons: Extensive deterioration

L15001, RTHBUN–293920
Vault Toilet in Buck Creek
21750 Marina Pl.
Moravia IA 52571
Landholding Agency: COE
Property Number: 31201630005
Status: Excess
Comments: Documented deficiencies: Doors and walls rotten; clear threat to physical safety.
Reasons: Extensive deterioration

L15002, RTHBUN–29322
Vault Toilet in Buck Creek
21646 Marina Pl
Moravia IA 52571
Landholding Agency: COE
Property Number: 31201630006
Status: Excess
Comments: Documented deficiencies: Doors and walls rotten; clear threat to physical safety.
Reasons: Extensive deterioration

Michigan

Elmwood Warehouse, ID #1311
Latitude 46.22691000, Longitude-088.91930000
Iron River MI 49935
Landholding Agency: Agriculture
Property Number: 15201630010
Status: Unutilized
Comments: Documented deficiencies: Extremely dilapidated; large hole in roof; SE corner of building is collapsing; crumbling sidewalls.
Reasons: Extensive deterioration

Nevada

6 Buildings
Sandia National Laboratories
Tonopah NV 89049
Landholding Agency: Energy
Property Number: 41201630003
Status: Excess
Directions: 03–71; 09–06; 03–87; 09–62; 18–50; 18–51
Comments: Public access denied and no alternative method to gain access without compromising national security.
Reasons: Secured Area

New York

Building 354 (SWAT Office)
Corner of NY Ave. & Battery Rd.
Ft. Wadsworth
Staten Island NY 10305
Landholding Agency: Interior
Property Number: 61201630013
Status: Excess
Comments: Documented deficiencies: Roof damage; structurally unsound; water damage due to Sandy.
Reasons: Extensive deterioration

Texas

Texoma-60606
351 Corps Rd.
Denison TX 75020
Landholding Agency: COE
Property Number: 31201630009
Status: Unutilized
Comments: Documented deficiencies: Damaged due to indented by high water; integrity of structure compromised; clear threat to physical safety.
Reasons: Extensive deterioration

Washington

Kachess Flush
Bakers Lane
Installation No. 07672 00
Cle Elum WA 98922
Landholding Agency: Agriculture
Property Number: 15201630011
Status: Underutilized
Directions: 14780TB1–1434.005511; 14780TB2–1435.005511; 14780TB3–1436.005511; 14780TB4–1437.005511; 14780TB5–1438.005511; 14780TB10–1443.005511
Comments: Floodway (Property located within floodway which has not been correct or contained).
Reasons: Floodway

[FR Doc. 2016–18871 Filed 8–11–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[16X LLCO910000 L16100000.DS0000 LXSISGPW0000]

Notice of Availability of the Gunnison Sage-Grouse Rangewide Draft Resource Management Plan Amendment and Draft Environmental Impact Statement, Colorado and Utah

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended (NEPA), and the Federal Land Policy and Management Act of 1976, as amended, the Bureau of Land Management (BLM) has prepared a Gunnison Sage-Grouse (GUSG) Rangewide Draft Resource Management Plan (RMP) Amendment and Draft Environmental Impact Statement (EIS) for the BLM field offices in southwest Colorado and southeast Utah, and by this notice is announcing the opening of the comment period.

DATES: To ensure that comments will be considered, the BLM must receive written comments on the Draft RMP Amendment/Draft EIS within 90 days of the date the Environmental Protection Agency publishes notice of the Draft RMP Amendment/Draft EIS in the **Federal Register**. The BLM will announce future meetings or hearings and any other public participation activities at least 15 days in advance through public notices, media releases and/or mailings.

ADDRESSES: You may submit comments related to the GUSG Rangewide Draft RMP Amendment/Draft EIS by any of the following methods:

- *Website: http://1.usa.gov/1Uusw8C.*
- *Email: gusg_amend@blm.gov.*
- *Fax:* 303–239–3699.
- *Mail:* Gunnison Sage-Grouse EIS, BLM Colorado State Office, 2850 Youngfield St., Lakewood, CO 80215.

Documents pertinent to this proposal may also be viewed at BLM offices in Colorado and Utah. For a list of the offices and their addresses, please see the **SUPPLEMENTARY INFORMATION** section below.

FOR FURTHER INFORMATION CONTACT: Roger Sayre, Project Manager, via telephone: 303–239–3709; at the BLM Colorado Southwest District Office (see address above); or via email: *rsayre@blm.gov.* You may contact Mr. Sayre to have your name added to our mailing list. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, seven days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The BLM prepared the GUSG Rangewide Draft RMP Amendment/Draft EIS to address a range of alternatives focused on specific conservation measures across the range of the GUSG in southwest Colorado and southeast Utah. The Draft RMP Amendment/Draft EIS proposes to amend the current management decisions for resources as described in the following RMPs:

- Colorado
  - San Luis RMP (1991)
  - Gunnison RMP (1993)
  - San Juan/San Miguel RMP (1985) (currently under revision in the Uncompahgre RMP)
  - Uncompahgre Basin RMP (1989) (currently under revision in the Dominquez-Escalante National Conservation Area [NCA] RMP and Uncompahgre RMP)
  - Grand Junction RMP (1987) (Currently under revision in the Dominquez-Escalante NCA RMP)
  - Grand Junction RMP (2015)
  - Gunnison Gorge NCA RMP (2004)
  - Canyons of the Ancients National Monument RMP (2010)
  - Tres Rios RMP (2015)
- Utah
  - Moab RMP (2008)
  - Monticello RMP (2008)

The planning area includes approximately 2.1 million acres of BLM, National Park Service, U.S. Forest Service, State, local and private lands located in southwestern Colorado and southeastern Utah within 12 counties (Chaffee, Delta, Dolores, Gunnison, Hinsdale, Mesa, Montrose, Ouray, Saguache and San Miguel counties in Colorado; and Grand and San Juan counties in Utah). Within the decision area, the BLM administers approximately 740,000 surface acres and approximately 1.3 million acres of Federal sub-surface mineral estate. Within the decision area, the BLM manages 623,000 acres of GUSG habitat, representing 37 percent of the habitat across the species range. Surface and subsurface management decisions made as a result of this Draft RMP Amendment/Draft EIS will apply only to the BLM-administered lands and minerals in the decision area.

The Draft RMP Amendment/Draft EIS analyzes management actions applicable to three categories of BLM-administered lands and Federal subsurface: Occupied Habitat, Unoccupied Habitat, and Non-Habitat.

Occupied Habitat:

- Occupied critical habitat as designated by the Fish and Wildlife Service (FWS);
- Vacant/unknown habitat delineated by Colorado Parks and Wildlife that FWS did not designate as occupied critical habitat;
- Habitat within the Poncha Pass area; and
- Specific areas the FWS excluded from the critical habitat designation coinciding with Federal subsurface estate.

Unoccupied Habitat: Unoccupied critical habitat as designated by the FWS.

Non-Habitat: Non-GUSG habitat adjacent to Occupied or Unoccupied Habitat within 4 miles of a lek, where certain activities might disrupt GUSG within the adjacent habitat areas.

The formal public scoping process for the RMP Amendment/EIS began on July 18, 2014, with the publication of a Notice of Intent in the **Federal Register** (79 FR 42033), and ended on August 22, 2014. The BLM held four public scoping meetings in August 2014. The BLM used public scoping comments to help identify planning issues that directed the formulation of alternatives and framed the scope of analysis in the Draft RMP Amendment/Draft EIS. The BLM also used the scoping process to introduce the public to preliminary planning criteria, which set limits on the scope of the Draft RMP Amendment/Draft EIS.

Major issues the Draft RMP Amendment/Draft EIS considers include special status species management (specifically for the GUSG), energy and mineral development, lands and realty, travel and transportation, recreation, fire management and range management.

The Draft RMP Amendment/Draft EIS evaluates four alternatives in detail, including the No Action Alternative (Alternative A) and three action alternatives (Alternatives B, C and D). All action alternatives require compliance with the mitigation hierarchy of first, avoiding impacts to the maximum extent compatible with the goals of the alternative; second, minimizing any impacts that are not avoided; and third, providing compensatory mitigation to offset unavoidable impacts. All mitigation requires a net conservation gain. Alternative A, the No Action Alternative, would continue management of public lands and resources under current BLM RMPs, as previously amended. Alternative B primarily focuses on habitat protection and avoiding impacts to GUSG and GUSG habitat whenever and wherever possible. Alternative C focuses on minimizing and mitigating impacts to GUSG habitat. Alternative D, the Preferred Alternative, includes two sub-alternatives. Sub-alternative D_1 adapts and expands on the BLM Gunnison Basin Candidate Conservation Agreement (2013) to manage the Gunnison Basin GUSG population. Sub-alternative D_2 includes management actions developed and tailored for the satellite (non-Gunnison Basin) populations. Identification of a Preferred Alternative does not represent final agency decision, and the Proposed and Approved RMP Amendments may reflect changes or adjustments based on public comments, new information, or changes in BLM policies or priorities. The Proposed and Approved RMP Amendments may include objectives and actions described in the other analyzed alternatives or otherwise within the spectrum of alternatives analyzed. Pursuant to 43 CFR 1610.7–2(b), this notice announces a concurrent public comment period on proposed Areas of Critical Environmental Concern (ACECs). BLM determined that four potential ACECs met the criteria for relevance and importance, some of which overlapped. The Draft RMP Amendment/Draft EIS includes a range of alternatives for ACECs from no designations to designation of a single proposed ACEC that encompasses all four potential ACECs. In particular, Alternative B analyzes an ACEC for all Occupied and Unoccupied Habitat (the Sage-Grouse Habitat ACEC), which encompasses all four potential ACECs that were evaluated. This proposed ACEC covers approximately 623,000 acres and meets the relevance and importance criteria because it includes more than locally significant qualities for GUSG, which are threatened and warrant protection. If the Sage-Grouse Habitat ACEC is formally designated, all resource management actions in Alternative B would be applied. The following are the overarching use allocations: closed to fluid mineral leasing; designated as a right-of-way exclusion area; limited to travel on existing or designated roads and trails; and recommended for withdrawal from mineral entry.

Please note that public comments and information submitted including names, street addresses and email addresses of persons who submit comments will be available for public review and disclosure at the above addresses during regular business hours (8 a.m. to 4 p.m.), Monday through Friday, except holidays.

In addition to the Web site listed above, documents pertinent to this proposal may be examined at:

- BLM Colorado State Office (see **ADDRESSES** above)
- BLM Colorado Southwest District Office, 2465 South Townsend Ave., Montrose, CO 81401
- BLM Colorado Grand Junction Field Office, 2815 H Road, Grand Junction, CO 81506
- BLM Colorado Gunnison Field Office, 210 West Spencer Ave., Gunnison, CO 81230
- BLM Colorado San Luis Valley Field Office, 1313 E. Highway 160, Monte Vista, CO 81144

- BLM Colorado Tres Rios Field Office, 29211 Highway 184, Dolores, CO 81323
- BLM Utah State Office, 440 West 200 South, Suite 500, Salt Lake City, UT 84101
- BLM Utah Canyon County District Office, 82 East Dogwood, Moab, UT 84532
- BLM Utah Monticello Field Office, 365 N. Main St., Monticello, UT 84535.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 40 CFR 1506.6, 40 CFR 1506.10, 43 CFR 1610.2

Ruth Welch,

BLM Colorado State Director.

[FR Doc. 2016–19100 Filed 8–11–16; 8:45 am]

BILLING CODE 4310–JB–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–16–028]

Government in the Sunshine Act Meeting Notice

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: August 17, 2016 at 11:00 a.m.

PLACE: Room 101, 500 E Street SW., Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agendas for future meetings: None.
2. Minutes.
3. Ratification List.
4. Vote in Inv. Nos. 701–TA–539 and 731–TA–1280–1282 (Final)(Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from Korea, Mexico, and Turkey). The Commission is currently scheduled to complete and file its determinations and views of the Commission on September 6, 2016.
5. Outstanding action jackets: None.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.

Issued: August 10, 2016.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016–19407 Filed 8–10–16; 4:15 pm]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–975]

Certain Computer Cables, Chargers, Adapters, Peripheral Devices and Packaging Containing the Same; Notice of To Review an Initial Determination Finding All Respondents in Default; Request for Written Submissions on Remedy, the Public Interest, and Bonding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review the presiding administrative law judge's ("ALJ") initial determination ("ID") (Order No. 7) finding all respondents in default. The Commission requests written submissions, under the schedule set forth below, on remedy, public interest, and bonding.

FOR FURTHER INFORMATION CONTACT: Amanda Pitcher Fisherow, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2737. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on December 17, 2015, based on a complaint filed on behalf of Belkin International, Inc. of Playa Vista, California ("Complainant"). 80 *Fed. Reg.* 78763–64 (December 17, 2015). The complaint alleges violations of Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the sale for importation, importation, or sale within the United States after importation of certain computer cables, chargers, adapters, peripheral devices and packaging containing the same by reason of infringement of one or more of U.S. Trademark Registration No. 2,339,459; U.S. Trademark Registration No. 2,339,460; U.S. Trademark Registration No. 4,168,379; and U.S. Trademark Registration No. 4,538,212. The Commission's notice of investigation named the following respondents: Dongguan Pinte Electronic Co., Ltd., of Dongguan City, China; and Dongguan Shijie Fresh Electronic Products Factory, of Dongguan City, China (collectively "Respondents"). The Office of Unfair Import Investigations was named as a party.

On June 6, 2016, Complainant moved to find Respondents in default. The Commission investigative attorney filed a response in support of Complainant's motion. On June 21, 2016, the ALJ issued Order No. 6 ordering Respondents to show cause why they should not be found in default for failing to file a response to the complaint and notice of investigation.

On July 12, 2016, the ALJ issued the subject ID finding Respondents in default. *See* Order No. 7. No petitions for review of the ID were filed.

The Commission has determined not to review the subject ID.

Section 337(g)(1) and Commission Rule 210.16(c) authorize the Commission to order relief against a respondent found in default, unless, after considering the public interest, it finds that such relief should not issue. Complainant seeks a limited exclusion order and a cease and desist order.

In connection with the final disposition of this investigation, the Commission may: (1) Issue an order that could result in the exclusion of articles manufactured or imported by the defaulting respondent; and/or (2) issue a cease and desist order that could result in the defaulting respondent being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *Certain Devices for*

Connecting Computers via Telephone Lines, Inv. No. 337–TA–360, USITC Pub. No. 2843, Comm'n Op. at 7–10 (December 1994).

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors that the Commission will consider include the effect that the exclusion order and/or cease and desists orders would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve or disapprove the Commission's action. *See* Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

Written Submissions: Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Complainant is also requested to state the HTSUS numbers under which the accused products are imported. Complainant is further requested to supply the names of known importers of the products at issue in this investigation.

The written submissions and proposed remedial orders must be filed no later than close of business on August 18, 2016. Reply submissions must be filed no later than the close of business on August 25, 2016. No further submissions on these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the investigation number ("Inv. No. 337–TA–975") in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf*). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,[1] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: August 8, 2016.

William R. Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2016–19188 Filed 8–11–16; 8:45 am]

BILLING CODE 7020–02–P

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[1] All contract personnel will sign appropriate nondisclosure agreements.

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Humanities

Meetings of Humanities Panel

AGENCY: National Endowment for the Humanities, National Foundation on the Arts and the Humanities.

ACTION: Notice of meetings.

SUMMARY: The National Endowment for the Humanities will hold nine meetings of the Humanities Panel, a federal advisory committee, during September, 2016. The purpose of the meetings is for panel review, discussion, evaluation, and recommendation of applications for financial assistance under the National Foundation on the Arts and Humanities Act of 1965.

DATES: See **SUPPLEMENTARY INFORMATION** section for meeting dates. The meetings will open at 8:30 a.m. and will adjourn by 5:00 p.m. on the dates specified below.

ADDRESSES: The meetings will be held at the National Endowment for the Humanities at Constitution Center at 400 7th Street SW., Washington, DC 20506.

FOR FURTHER INFORMATION CONTACT: Elizabeth Voyatzis, Committee Management Officer, 400 7th Street SW., Room 4060, Washington, DC 20506; (202)606–8322; *evoyatzis@neh.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. App.), notice is hereby given of the following meetings:

1. *Date:* September 1, 2016.

This meeting will discuss applications on the subject of International Topics for Digital Projects for the Public: Discovery Grants, submitted to the Division of Public Programs.

2. *Date:* September 6, 2016.

This meeting will discuss applications on the subjects of Arts and Culture for Digital Projects for the Public: Discovery Grants, submitted to the Division of Public Programs.

3. *Date:* September 7, 2016.

This meeting will discuss applications on the subjects of Arts and Culture for Digital Projects for the Public: Production Grants, submitted to the Division of Public Programs.

4. *Date:* September 8, 2016.

This meeting will discuss applications on the subject of U.S. History for Digital Projects for the Public: Production Grants, submitted to the Division of Public Programs.

5. *Date:* September 12, 2016.

This meeting will discuss applications for the Humanities Initiatives at Hispanic-Serving Institutions grant program, submitted to the Division of Education Programs.

6. *Date:* September 13, 2016.

This meeting will discuss applications for the Humanities Initiatives at Historically Black Colleges and Universities grant program, submitted to the Division of Education Programs.

7. *Date:* September 13, 2016.

This meeting will discuss applications on the subjects of World History and Culture for Digital Projects for the Public: Production Grants, submitted to the Division of Public Programs.

8. *Date:* September 14, 2016.

This meeting will discuss applications on the subject of U.S. History for Digital Projects for the Public: Production Grants, submitted to the Division of Public Programs.

9. *Date:* September 14, 2016.

This meeting will discuss applications for the Humanities Initiatives at Tribal Colleges and Universities grant program, submitted to the Division of Education Programs.

Because these meetings will include review of personal and/or proprietary financial and commercial information given in confidence to the agency by grant applicants, the meetings will be closed to the public pursuant to sections 552b(c)(4) and 552b(c)(6) of Title 5, U.S.C., as amended. The Committee Management Officer, Elizabeth Voyatzis, has made this determination pursuant to the authority granted her by the Chairman's Delegation of Authority to Close Advisory Committee Meetings dated April 15, 2016.

Dated: August 8, 2016.

Michael P. McDonald,

General Counsel and Federal Register Liaison Officer.

[FR Doc. 2016–19204 Filed 8–11–16; 8:45 am]

BILLING CODE 7536–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2016–0160]

Termination of Operating Licenses for Nuclear Reactors

AGENCY: Nuclear Regulatory Commission.

ACTION: Regulatory guide; withdrawal.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is withdrawing Regulatory Guide (RG) 1.86, "Termination of Operating Licenses for Nuclear Reactors." This RG is being withdrawn because there is more up-to-date guidance in other NRC regulatory documents, making RG 1.86 obsolete.

DATES: The effective date of the withdrawal of RG 1.86 is August 12, 2016.

ADDRESSES: Please refer to Docket ID NRC–2016–0160 when contacting the, NRC about the availability of information regarding this document. You may obtain publically-available information related to this document, using the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0160. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Document collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select "ADAMS Public Documents" and then select "*Begin Web-based ADAMS Search.*" For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced in this notice (if that document is available in ADAMS) is provided the first time that a document is referenced. The basis for the withdrawal of RG 1.86 is available in ADAMS under Accession No. ML16099A267.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

Regulatory guides are not copyrighted, and NRC approval is not required to reproduce them.

FOR FURTHER INFORMATION CONTACT: Zahira Cruz, Office of Nuclear Materials Safety and Safeguards, telephone: 301–415–3808; email: *Zahira.Cruz@nrc.gov,* and Harriet Karagiannis, Office of Nuclear Regulatory Research, telephone: 301–415–2493; email: *Harriet.Karagiannis@nrc.gov.* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION: The NRC staff issued RG 1.86 in June 1974, to provide guidance for termination of licenses for nuclear power plants, including the decommissioning of reactors. In addition, RG 1.86 includes information in Table 1, "Acceptable Surface Contamination Levels," regarding acceptable average and maximum surface contamination criteria.

The guidance in RG 1.86 is no longer needed because it has been updated and replaced by NRC's regulations and other regulatory guidance. This guidance can be found in RG 1.179, "Standard Formant and Content of License Termination Plans for Nuclear Power Reactors" (ADAMS Accession No. ML110490419); RG 1.184, "Decommissioning of Nuclear Power Reactors" (ADAMS Accession No. ML13144A840); and RG 1.185, "Standard Format and Content for Post-Shutdown Decommissioning Activities Report" (ADAMS Accession No. ML13140A038), which provide the NRC staff guidance on implementing the NRC's regulations related to decommissioning and license termination requirements as amended in 1996 and 1997, respectively.

In addition, various NUREGs, including NUREG–1700, "Standard Review Plan for Evaluating Nuclear Power Reactor License Termination Plans" (ADAMS Accession No. ML003713038; and Volume 2, "Characterization, Survey, and Determination of Radiological Criteria" (ADAMS Accession No. ML032530405), of NUREG–1757, "Consolidated Decommissioning Guidance," provide up-to-date information that aligns with RGs 1.179, 1.184, and 1.185. Specifically, NUREG 1757, Volume 2, Revision 1, includes: (1) Tables of screening criteria (concentrations) applicable to surface contamination of buildings and to surface soils (Tables H.1 and H.2); and (2) guidance on determining site-specific criteria for buildings and soils remaining onsite at license termination (Chapter 5 and Appendix I).

Also, RG 8.21, "Health Physics Surveys for Byproduct Material at NRC-Licensed Processing and Manufacturing Plants" (ADAMS Accession No. ML003739577); RG 8.23, "Radiation Safety Surveys at Medical Institutions" (ADAMS Accession No. ML003739603); and RG 8.30, "Health Physics Surveys in Uranium Recovery Facilities" (ADAMS Accession No. ML021260524), provide information similar to that included in Table 1 of RG 1.86. Specifically, Table 1 in RG 1.86 is now included in RG 8.23 and is titled, "Table 3 Acceptable Surface Contamination Levels for Uncontrolled Release of Equipment."

Because RG 1.86 is no longer needed, the NRC is withdrawing RG 1.86. Withdrawal of a RG means that the guide no longer provides useful information or has been superseded by other guidance, technological innovations, congressional actions, or other events. The withdrawal of RG 1.86 does not alter any prior or existing NRC licensing approval or the acceptability of licensee commitments to RG 1.86.

Although RG 1.86 is withdrawn, current licensees may continue to use it, and withdrawal does not affect any existing licenses or agreements. However, RG. 1.86 should not be used in future requests or applications for NRC licensing actions.

Dated at Rockville, Maryland, this 4th day of August, 2016.

For the Nuclear Regulatory Commission.

Thomas H. Boyce,

Chief, Regulatory Guidance and Generic Issues Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2016–19195 Filed 8–11–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2016–0054]

License Amendment Requests for Changes to Emergency Response Organization Staffing and Augmentation

AGENCY: Nuclear Regulatory Commission.

ACTION: Regulatory issue summary; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing Regulatory Issue Summary (RIS) 2016–10, "License Amendment Requests for Changes to Emergency Response Organizations Staffing and Augmentation." This RIS clarifies the application of guidance documents that support license amendment requests that would change augmenting emergency response arrival times for holders of nuclear power reactor operating licenses, construction permits, combined licenses, and early site permits.

DATES: The RIS is available as of August 12, 2016.

ADDRESSES: Please refer to Docket ID NRC–2016–0054 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0054. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select "*ADAMS Public Documents*" and then select "*Begin Web-based ADAMS Search.*" For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The RIS, "License Amendment Requests for Changes to Emergency Response Organization Staffing and Augmentation," is available in ADAMS under Accession No. ML16124A002.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.
- This RIS is also available on the NRC's public Web site at *http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/* (select "2016" and then select "RIS–16–10").

FOR FURTHER INFORMATION CONTACT: Brian K. Harris, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2277, email: *Brian.Harris2@nrc.gov.*

SUPPLEMENTARY INFORMATION: The NRC published a notice of opportunity for public comment on a draft version of this RIS in the **Federal Register** on March 15, 2016 (81 FR 13849), and received comments from three commenters. The NRC staff considered all comments, which resulted in minor RIS modifications. The evaluation of these comments and the resulting changes to the RIS are discussed in a publicly-available memorandum, which is in ADAMS under Accession No. ML16124A001.

Dated at Rockville, Maryland, this 8th day of August 2016.

For the Nuclear Regulatory Commission.

Alex Garmoe,

Acting Chief, Generic Communications Branch, Division of Policy and Rulemaking, Office of Nuclear Reactor Regulation.

[FR Doc. 2016–19212 Filed 8–11–16; 8:45 am]

BILLING CODE 7590–01–P

PRESIDIO TRUST

Notice of Public Meeting of Presidio Institute Advisory Council

AGENCY: The Presidio Trust.

ACTION: Notice of public meeting of Presidio Institute Advisory Council.

SUMMARY: Pursuant to the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given that a public meeting of the Presidio Institute Advisory Council (Council) will be held from 10:00 a.m. to 11:30 a.m. on Monday, September 12, 2016. The meeting is open to the public, and oral public comment will be received at the meeting. The Council was formed to advise the Executive Director of the Presidio Trust (Trust) on matters pertaining to the rehabilitation and reuse of Fort Winfield Scott as a new national center focused on service and leadership development.

SUPPLEMENTARY INFORMATION: The Trust's Executive Director, in consultation with the Chair of the Board of Directors, has determined that the Council is in the public interest and supports the Trust in performing its duties and responsibilities under the Presidio Trust Act, 16 U.S.C. 460bb appendix.

The Council will advise on the establishment of a new national center (Presidio Institute) focused on service and leadership development, with specific emphasis on: (a) Assessing the role and key opportunities of a national center dedicated to service and leadership at Fort Scott in the Presidio of San Francisco; (b) providing recommendations related to the Presidio Institute's programmatic goals, target audiences, content, implementation and evaluation; (c) providing guidance on a phased development approach that leverages a combination of funding sources including philanthropy; and (d) making recommendations on how to structure the Presidio Institute's business model to best achieve the Presidio Institute's mission and ensure long-term financial self-sufficiency.

Meeting Agenda: This meeting of the Council will include an update on Presidio Institute programs. The period from 11:00 a.m. to 11:30 a.m. will be reserved for public comments.

Public Comment: Individuals who would like to offer comments are invited to sign-up at the meeting and speaking times will be assigned on a first-come, first-served basis. Written comments may be submitted on cards that will be provided at the meeting, via mail to Amanda Marconi, Presidio Institute, 1201 Ralston Avenue, San Francisco, CA 94129–0052, or via email to *amarconi@presidiotrust.gov.* If individuals submitting written comments request that their address or other contact information be withheld from public disclosure, it will be honored to the extent allowable by law. Such requests must be stated prominently at the beginning of the comments. The Trust will make available for public inspection all submissions from organizations or businesses and from persons identifying themselves as representatives or officials of organizations and businesses.

Time: The meeting will be held from 10:00 a.m. to 11:30 a.m. on Monday, September 12, 2016.

Location: The meeting will be held at 1202 Ralston Avenue, San Francisco, CA 94129.

FOR FURTHER INFORMATION CONTACT: Additional information is available online at *http://www.presidio.gov/institute/about/Pages/advisory-council.aspx*

Dated: August 8, 2016.

Andrea M. Andersen,

Acting General Counsel.

[FR Doc. 2016–19200 Filed 8–11–16; 8:45 am]

BILLING CODE 4310–4R–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–72, OMB Control No. 3235–0076]

Submission for OMB Review; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736.

Extension:

Form D and Regulation D.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (“Commission”) has submitted to the Office of Management and Budget this request for extension of the previously approved collection of information discussed below.

Form D (17 CFR 239.500) is a notice of sales filed by issuers making an offering of securities in reliance on an exemption under Regulation D (17 CFR 230.501 *et seq.*) or Section 4(a)(5) of the Securities Act of 1933 (15 U.S.C. 77d(a)(5)). Regulation D sets forth rules governing the limited offer and sale of securities without Securities Act registration. The purpose of Form D is to collect empirical data, which provides a continuing basis for action by the Commission either in terms of amending existing rules and regulations or proposing new ones. In addition, the Form D allows the Commission to elicit information necessary in assessing the effectiveness of Regulation D (17 CFR 230.501 *et seq.*) and Section 4(6) of the Securities Act of 1933 (15 U.S.C. 77d(6)) as capital-raising devices for all businesses. Form D information is required to obtain or retain benefits under Regulation D. Approximately 21,686 issuers file Form D and it takes approximately 4 hours per response. We estimate that 25% of the 4 hours per response (1 hour per response) is prepared by the issuer for an annual reporting burden of 21,686 hours (1 hour per response × 21,686 responses).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

The public may view the background documentation for this information collection at the following Web site, *www.reginfo.gov* . Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: August 5, 2016.

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–19182 Filed 8–11–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78502; File No. SR–IEX–2016–10]

Self-Regulatory Organizations: Investors Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 9.218 To Specify the List of Violations Eligible for Disposition Under IEX's Minor Rule Violation Plan

August 8, 2016.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (“Act”)[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on August 4, 2016, the Investors Exchange LLC (“IEX” or “Exchange”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Pursuant to the provisions of Section 19(b)(1) under the Securities Exchange Act of 1934 (“Act”) [sic],[4] and Rule 19b–4 thereunder,[5] Investors Exchange LLC (“IEX” or “Exchange”) [sic] is filing with the Securities and Exchange Commission (“Commission”) [sic] a proposed rule change to amend IEX Rule 9.218 (Violations Appropriate for Disposition Under Plan Pursuant to Exchange Act Rule 19d–1(c)(2)) to specify the list of violations eligible for disposition under IEX Rule 9.216(b), (Procedure for Violation Under Plan Pursuant to Exchange Act Rule 19d–1(c)(2)) pursuant to IEX's Minor Rule Violation Plan (“MRVP”).[6] The Exchange has designated this proposal as non-controversial and provided the Commission with the notice required by Rule 19b–4(f)(6)(iii) under the Act.[7]

The text of the proposed rule change is available at the Exchange's Web site at *www.iextrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statement [sic] may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

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[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] 15 U.S.C. 78s(b)(1).

[5] 17 CRF 240.19b–4.

[6] IEX's MRVP was declared effective by the Commission on August 3, 2016. *See,* Securities Exchange Act Release No. 78474 (August 3, 2016).

[7] 17 CFR 240.19b–4(f)(6)(iii).

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

IEX Rule 9.216(b) provides procedures for disposition of certain rule violations designated as minor rule violations pursuant to a plan declared effective by the Commission in accordance with Section 19(d)(1) of the Act and Rule 19d–1(c)(2) thereunder. IEX's MRVP allows IEX, or FINRA on its behalf, to impose a fine of up to $2,500 on any Member or associated person of a Member for a minor violation of an eligible rule. As proposed, IEX Rule 9.218 sets forth the rules eligible for disposition pursuant to IEX's MRVP as well as the recommended fine schedule for such dispositions. While IEX considers compliance with all of its rules to be important, inclusion of more technical rule violations in the MRVP is designed to provide for a risk-based allocation of FINRA and IEX resources to more high-risk matters because MRVP settlements are typically handled more efficiently and expeditiously.

The purpose of the MRVP is to provide reasonable but meaningful sanctions for minor or technical violations of rules when the conduct at issue does not warrant stronger, reportable disciplinary sanctions. The inclusion of a rule in IEX's MRVP does not minimize the importance of compliance with such rule, nor does it preclude IEX, or FINRA on its behalf, from choosing to pursue violations of eligible rules through an Acceptance, Waiver and Consent ("AWC") or Complaint if the nature of the violations or prior disciplinary history warrants more significant sanctions. Rather, the option to impose an MRVP sanction gives IEX, and FINRA on its behalf, additional flexibility to administer its enforcement program in the most effective and efficient manner, while still fully meeting IEX's remedial objectives in addressing violative conduct. FINRA, on behalf of IEX, and subject to IEX oversight, will examine and surveil for compliance with MRVP eligible rules in a manner consistent with the IEX regulatory program and will determine on a case-by-case basis whether disposition pursuant to the MRVP is appropriate.

In addition, Members and their associated persons may decline to accept a Minor Rule Violation, in which case FINRA, on behalf of IEX, may proceed in accordance with the Exchange's disciplinary rules, which include hearing rights for formal disciplinary proceedings.[8]

IEX conducted a comprehensive review of its rules to determine the rules that are appropriate to add to the MRVP. As proposed, the rules included in the MRVP are as follows:

- *Continuing education:* Rule 2.160(p) specifies the continuing education requirements applicable to registered representatives of Members. Both FINRA and the Nasdaq Stock Market ("Nasdaq") include comparable rules in each of their MRVPs.[9]
- *Books and records:* Rule 4.511 requires IEX Members to comply with FINRA Rule 4511 as if such rule were part of the Exchange's rules, and specifies applicable books and records requirements. FINRA Rule 4511 is included in FINRA's MRVP.
- *Furnishing of records:* Rule 4.540 requires IEX Members to furnish specified records to the Exchange, upon request and in a time and manner required by the Exchange. The rule also provides that the Exchange shall be allowed access, at any time, to the books and records of the Member in order to obtain or verify information related to transactions executed on or through the Exchange or activities relating to the Exchange. This rule is comparable to BATS BZX Exchange, Inc. ("BZX") Rule 4.2, which is included in the BZX MRVP.[10]
- *Supervision:* Rule 5.110 requires that each Member establish and maintain a system to supervise the activities of each associated person that is reasonably designed to achieve compliance with applicable securities laws and regulations, and with applicable IEX rules; including, as specified, written procedures, internal inspections, transaction review and investigation, and investigation of applicants for registration. Violations of Rule 5.110 would be included in the MRVP where the underlying violative conduct is also included in the MRVP.[11] FINRA treats its comparable Rule 3110 in the same manner.
- *Automated submission of trading data requested:* Rule 8.220 requires Members to submit trade data in the specified automated format upon request by IEX. This rule is comparable to FINRA Rule 8211 which is included in FINRA's MRVP.
- *Market Maker two-sided quotation requirement:* Rule 11.151(a)(1) requires that a Member registered as a Market Maker comply with the specified continuous two-sided quotations requirements. This rule is comparable to BZX Rule 11.8(a)(1) which is included in BZX MRVP.
- *Short sales:* Rule 11.290 requires, among other things, that all sell orders be marked long, short, or short exempt. FINRA includes Rule 200(g) of SEC Regulation SHO (Failure to accurately mark sell orders of equity securities) in its MRV. Similarly, BZX includes its Rule 11.19 requirement to identify short sale orders as such in its MRV plan.
- *Locking or crossing quotations in NMS stocks:* Rule 11.310 provides in relevant part that Users of IEX shall reasonably avoid displaying, and shall not engage in a pattern or practice of displaying, any quotations that lock or cross a protected quotation previously disseminated pursuant to an effective national market system plan. This rule is comparable to BZX Rule 11.20, which is included in BZX MRVP.
- *Order audit trail system requirements:* Rule 11.420 specifies the order audit trail system requirements applicable to Members and persons associated with a Member, and in relevant part also requires compliance with FINRA Rules 7440 and 7550 as if such rule were part of IEX's rules. This rule is comparable to Nasdaq Rules 6954 and 6955,[12] as well as FINRA Rules 7440 and 7450, each of which are included in the Nasdaq and FINRA MRVP.

In addition, as proposed, Rule 9.218 includes the following recommended fine schedule for minor rule violation dispositions of the rules included therein:

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[8] *See,* Chapter 9 generally.

[9] See FINRA Rules 9217 and 1250, Nasdaq Rules 1120 and IM–9216.

[10] *See* BZX Rule 8.15.

[11] For example, if FINRA (on behalf of IEX) identified that a short sale order marking violation (Rule 11.290) was attributable to a supervision deficiency, the supervision deficiency could be included in a disposition under the MRVP.

[12] Nasdaq Rules 6954 and 6955 were renumbered as Rules 7440A and 7450A respectively.

Occurrence *	Individual	Member
First time fined	$100	$500
Second time fined	300	1,000
Third time fined	500	2,500

* Within a "rolling" 12-month period.

The recommended fine schedule is based on BZX Rule 8.15, Interpretations and Policies .01. The recommended fine schedule is intended to provide transparency to IEX Members and associated persons with respect to administration of the Exchange's MRVP.

2. Statutory Basis

IEX believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[13] in general, and furthers the objectives of Sections 6(b)(5),[14] (6)[15] and (7)[16] of the Act, in particular.

The Exchange believes that the proposal is consistent with Section 6(b)(5) of the Act[17] because it is designed to promote just and equitable principles of trade, remove impediments to, and perfect the mechanism of, a free and open market and a national market system, and, in general, protect investors and the public interest. Specifically, the proposed rule change will provide the Exchange with the ability to impose reasonable but meaningful sanctions for minor or technical violations of rules when the conduct at issue does not warrant stronger, reportable disciplinary sanctions, which is consistent with the protection of investors and the public interest. Further, the Exchange believes that inclusion of the specified rules in the Exchange's MRVP, as well as the recommended fine schedule, would provide FINRA, on behalf of the Exchange, with the ability to administer its enforcement program in the most effective and efficient manner, while still fully meeting IEX's remedial objectives in addressing violative conduct, which is also consistent with the protection of investors and the public interest.

In addition, the Exchange believes that the proposal is consistent with Section 6(b)(7) of the Act[18] because it would provide a fair procedure for the disciplining of IEX Members and associated persons. As discussed above, under the Exchange's disciplinary rules a Member or associated person may decline to accept a Minor Rule Violation, in which case FINRA, on behalf of IEX, may proceed in accordance with the Exchange's disciplinary rules, which include hearing rights for formal disciplinary proceedings. The Exchange's rules governing formal disciplinary rules have already been approved by the Commission, which included a finding that IEX's rules concerning its disciplinary and oversight programs are consistent with the requirements of Sections 6(b)(6) and 6(b)(7) of the Act[19] in that they provide fair procedures for the disciplining of members and persons associated with members.[20]

The Exchange also believes that the proposed rule change does not unfairly discriminate between customers, issuers, brokers and dealers in that it will be applicable to all Members.

B. Self-Regulatory Organization's Statement on Burden on Competition

IEX does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change will allow for a quicker, more efficient means to resolve minor violations of eligible rules, potentially lessening the burden on firms in those circumstances where, absent the rule's inclusion in the MRVP, a more resource-intense formal process might ensue.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act[21] and Rule 19b–4(f)(6) thereunder.[22] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[23] and Rule 19b–4(f)(6) thereunder.[24]

A proposed rule change filed under Rule 19b–4(f)(6)[25] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[26] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative at the time of the launch of its operation as a national securities exchange.

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. As noted above, the IEX MRVP, including the proposed violations, was declared effective by the Commission on August 3, 2016.[27] The proposed rule change merely incorporates the list of violations included in the MRVP into IEX Rule 9.218. For this reason, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.[28]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

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[13] 15 U.S.C. 78f.

[14] 15 U.S.C. 78f(b)(5).

[15] 15 U.S.C. 78f(b)(6).

[16] 15 U.S.C. 78f(b)(7).

[17] *See supra* note 14 [sic].

[18] *See supra* note 16 [sic].

[19] *See supra,* notes 15 [sic] and 16 [sic].

[20] *See* Securities Exchange Act Release No. 34–78101 (June 17, 2016), 81 FR 41141 (June 23, 2016) (File No. 10–222).

[21] 15 U.S.C. 78s(b)(3)(A).

[22] 17 CFR 240.19b–4(f)(6).

[23] 15 U.S.C. 78s(b)(3)(A).

[24] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[25] 17 CFR 240.19b–4(f)(6).

[26] 17 CFR 240.19b–4(f)(6)(iii).

[27] *See supra* note 6.

[28] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–IEX–2016–10 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–IEX–2016–10. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–IEX–2016–10, and should be submitted on or before September 2, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[29]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–19171 Filed 8–11–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 32209; File No. 812–14497]

Blackrock Funds, et al.; Notice of Application

August 8, 2016.

AGENCY: Securities and Exchange Commission ("Commission").

ACTION: Notice of an application for an order pursuant to: (a) Section 6(c) of the Investment Company Act of 1940 ("Act") granting an exemption from sections 18(f) and 21(b) of the Act; (b) section 12(d)(1)(J) of the Act granting an exemption from section 12(d)(1) of the Act; (c) sections 6(c) and 17(b) of the Act granting an exemption from sections 17(a)(1), 17(a)(2) and 17(a)(3) of the Act; and (d) section 17(d) of the Act and rule 17d-1 under the Act to permit certain joint arrangements and transactions.

Summary of the Application: Applicants request an order that would permit certain registered open-end management investment companies to participate in a joint lending and borrowing facility.

Applicants: Blackrock Funds; Blackrock Funds II; BBIF Government Securities Fund; BBIF Money Fund; BBIF Tax-Exempt Fund; BBIF Treasury Fund; BIF Government Securities Fund; BIF Money Fund; BIF Multi-State Municipal Series Trust; BIF Tax-Exempt Fund; BIF Treasury Fund; Blackrock Emerging Markets Fund, Inc.; Blackrock Financial Institutions Series Trust; Blackrock Index Funds, Inc.; Blackrock Large Cap Series Funds, Inc.; Blackrock Latin America Fund, Inc.; Blackrock Liquidity Funds; Blackrock Master LLC; Blackrock Pacific Fund, Inc.; Blackrock Series, Inc.; Master Government Securities LLC; Master Large Cap Series LLC; Master Money LLC; Master Tax-Exempt LLC; Master Treasury LLC; Quantitative Master Series LLC; Ready Asset Government Liquidity Fund; Ready Assets U.S.A. Government Money Fund; Ready Assets U.S. Treasury Money Fund; Retirement Series Trust; Blackrock Allocation Target Shares; Blackrock Balanced Capital Fund, Inc.; Blackrock Basic Value Fund, Inc.; Blackrock Bond Fund, Inc.; Blackrock California Municipal Series Trust; Blackrock Capital Appreciation Fund, Inc.; Blackrock Cori Funds; Blackrock Equity Dividend Fund; Blackrock Eurofund; Blackrock Focus Growth Fund, Inc.; Blackrock Global Allocation Fund, Inc.; Blackrock Global Smallcap Fund, Inc., Blackrock Long-Horizon Equity Fund; Blackrock Mid Cap Value Opportunities Series, Inc.; Blackrock Multi-State Municipal Series Trust; Blackrock Municipal Bond Fund, Inc.; Blackrock Municipal Series Trust; Blackrock Natural Resources Trust; Blackrock Series Fund, Inc.; Blackrock Strategic Global Bond Fund, Inc.; Blackrock Value Opportunities Fund, Inc.; Blackrock Variable Series Funds, Inc.; FDP Series, Inc.; Managed Account Series; Master Bond LLC; Master Focus Growth LLC; Master Value Opportunities LLC; Blackrock Funds III; Master Investment Portfolio; Funds For Institutions Series; and Master Institutional Money Market LLC (together with each investment company listed in Exhibit A–1 to the application, a "Company" and collectively, the "Companies"); Blackrock Advisors, LLC and Blackrock Fund Advisors (each, an "Adviser," and together, the "Advisers").

DATES: The application was filed on June 26, 2015, and amended on November 20, 2015, May 13, 2016 and August 5, 2016.

Hearing or Notification of Hearing: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on September 2, 2016 and should be accompanied by proof of service on the applicants, in the form of an affidavit, or, for lawyers, a certificate of service. Pursuant to Rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090; Applicants: Benjamin Archibald, Esq., BlackRock Advisors, LLC, 55 East 52 Street, New York, NY 10055 and John A. MacKinnon, Esq., Sidley Austin LLP,

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[29] 17 CFR 200.30–3(a)(12), (59).

787 Seventh Avenue, New York, NY 10019.

FOR FURTHER INFORMATION CONTACT: Laura L. Solomon, Senior Counsel, at (202) 551–6915 or Daniele Marchesani, Branch Chief, at (202) 551–6821 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations

1. Each Company is organized as a Massachusetts business trust, a Delaware statutory trust, a Delaware limited liability company, or a Maryland corporation and is registered under the Act as an open-end management investment company. Each Company has issued shares of one or more series, each series of shares with its own distinct investment objectives, policies and restrictions. Certain of the Funds[1] either are or may be money market funds that comply with rule 2a–7 under the Act (each a "Money Market Fund" and collectively, the "Money Market Funds"). BlackRock Advisors is a Delaware limited liability company and BFA is a California corporation, each is registered as an investment adviser under the Investment Advisers Act of 1940 ("Advisers Act"). BlackRock Advisors and BFA are under common control by virtue of having the same ultimate parent, BlackRock, Inc.[2]

2. The Funds may lend cash to banks or other entities by entering into repurchase agreements or purchasing other short-term money market instruments. Certain of the Funds are parties to an unsecured revolving credit agreement with a group of lenders ("Credit Agreement"). The Funds may borrow under the Credit Agreement to meet shareholder redemptions and for other lawful purposes.

3. If Funds that experience a cash shortfall were to borrow under the Credit Agreement (or another credit facility), they would pay interest at a rate that is likely to be higher than the rate that could be earned by non-borrowing Funds on investments in repurchase agreements and other short-term money market instruments. Applicants assert the difference between the higher rate paid on a borrowing and what a bank pays to borrow under repurchase agreements or other arrangements represents the bank's profit for serving as the middleperson between a borrower and lender and is not attributable to any material difference in the credit quality or risk of such transactions.

4. The requested relief would permit the applicants to participate in an interfund lending facility ("InterFund Program") that would permit each Fund to lend money directly to and borrow money directly from other Funds for temporary purposes (each, an "InterFund Loan"). The Money Market Funds typically will not participate as borrowers under the InterFund Program. Applicants state that the requested relief will enable the Funds to access an available source of money and reduce costs incurred by the Funds that need to obtain loans for temporary purposes and permit those Funds that have uninvested cash available: (i) To earn a return on the money that they might not otherwise be able to invest; or (ii) to earn a higher rate of interest on investment of their short-term balances.

5. Applicants anticipate that the proposed InterFund Program would provide a borrowing Fund with a source of liquidity at a rate lower than the bank borrowing rate at times when the cash position of the Fund is insufficient to meet temporary cash requirements. This situation could arise when shareholder redemptions exceed anticipated volumes and certain Funds have insufficient cash on hand to satisfy such redemptions. When the Funds liquidate portfolio securities to meet redemption requests, they often do not receive payment in settlement for up to three days (or longer for certain foreign transactions). However, redemption requests normally are effected on the day following the trade date. The proposed InterFund Program would provide a source of immediate, short-term liquidity pending settlement of the sale of portfolio securities.

6. Applicants also anticipate that a Fund could use the InterFund Program when a sale of securities "fails" due to circumstances beyond the Fund's control, such as a delay in the delivery of cash to the Fund's custodian or improper delivery instructions by the broker effecting the transaction. "Sales fails" may present a cash shortfall if the Fund has undertaken to purchase a security using the proceeds from securities sold. Alternatively, the Fund could: (i) "Fail" on its intended purchase due to lack of funds from the previous sale, resulting in additional cost to the Fund; or (ii) sell a security on a same-day settlement basis, earning a lower return on the investment. Use of the InterFund Program under these circumstances would enable the Fund to have access to immediate short-term liquidity.

7. While bank borrowings and/or custodian overdrafts generally could supply Funds with a portion of the needed cash to cover unanticipated redemptions and sales fails, under the proposed InterFund Program, a borrowing Fund would pay lower interest rates than those that would be payable under short-term loans offered by banks or custodian overdrafts. In addition, Funds making short-term cash loans directly to other Funds would earn interest at a rate higher than they otherwise could obtain from investing their cash in repurchase agreements or certain other short term money market instruments. Thus, applicants assert that the proposed InterFund Program would benefit both borrowing and lending Funds.

8. The interest rate to be charged to the Funds on any Interfund Loan (the "InterFund Loan Rate") would be the average of the "Repo Rate" and the "Bank Loan Rate," both as defined below. The Repo Rate would be the highest current overnight repurchase agreement rate available to a lending Fund. The Bank Loan Rate for any day would be calculated by the InterFund Program Team, as defined below, on each day an InterFund Loan is made according to a formula established by each Fund's Board of Trustees, Board of Directors or Board of Managers, as applicable (each a "Board," and collectively the "Boards") intended to approximate the lowest interest rate at which a bank short-term loan would be available to the Fund. The formula would be based upon a publicly available rate (*e.g.,* Federal funds rate and/or LIBOR) plus an additional spread of basis points and would vary with this rate so as to reflect changing bank loan rates. The initial formula and any subsequent modifications to the formula would be subject to the approval of each Fund's Board. In addition, the Board of each Fund would

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[1] Applicants request that the order apply to the applicants and to any existing or future registered open-end management investment company or series thereof for which BlackRock Advisors or BFA or any successor thereto or an investment adviser controlling, controlled by, or under common control (within the meaning of section 2(a)(9) of the Act) with BlackRock Advisors or BFA or any successor thereto serves as investment adviser (each a "Fund" and collectively the "Funds" and each such investment adviser an "Adviser"). For purposes of the requested order, "successor" is limited to any entity that results from a reorganization into another jurisdiction or a change in the type of a business organization.

[2] All Funds that currently intend to rely on the requested order have been named as applicants. Any other Fund that relies on the requested order in the future will comply with the terms and conditions of the application.

periodically review the continuing appropriateness of reliance on the formula used to determine the Bank Loan Rate, as well as the relationship between the Bank Loan Rate and current bank loan rates that would be available to the Fund.

9. Certain members of the Adviser's and/or their affiliates' administrative and other personnel (the "InterFund Program Team"), which may include one or more investment professionals, including individuals involved in making investment decisions regarding short-term investments in the Money Market Funds ("Money Market portfolio managers"), would administer the InterFund Program. No portfolio manager of any Fund, (other than Money Market portfolio managers) would serve as a member of the InterFund Program Team. Under the proposed InterFund Program, the portfolio managers for each participating Fund could provide standing instructions to participate daily as a borrower or lender. The InterFund Program Team on each business day would collect data on the uninvested cash and borrowing requirements of all participating Funds. Once the InterFund Program Team has determined the aggregate amount of cash available for loans and borrowing demand, the InterFund Program Team would allocate loans among borrowing Funds without any further communication from the portfolio managers of the Funds. All allocations made by the InterFund Program Team will require the approval by at least one member of the InterFund Program Team who is a high level employee, other than a Money Market portfolio manager. Applicants anticipate that there typically will be more available uninvested cash each day than borrowing demand. Therefore, after the InterFund Program Team has allocated cash for Interfund Loans, the InterFund Program Team will invest any remaining cash in accordance with the standing instructions of the relevant portfolio manager or such remaining amounts will be invested directly by the portfolio managers of the Funds.

10. The InterFund Program Team would allocate borrowing demand and cash available for lending among the Funds on what the InterFund Program Team believes to be an equitable basis, subject to certain administrative procedures applicable to all Funds, such as the time of filing requests to participate, minimum loan lot sizes, and the need to minimize the number of transactions and associated administrative costs. To reduce transaction costs, each InterFund Loan normally would be allocated in a manner intended to minimize the number of participants necessary to complete the loan transaction. The method of allocation and related administrative procedures would be approved by the Boards of the Funds, including a majority of the Board members who are not "interested persons," as defined in section 2(a)(19) of the Act ("Independent Board Members"), to ensure that both borrowing and lending Funds participate on an equitable basis.

11. The InterFund Program Team, on behalf of the Advisers, would: (a) Monitor the InterFund Loan Rate and the other terms and conditions of the InterFund Loans; (b) limit the borrowings and loans entered into by each Fund to ensure that they comply with the Fund's investment policies and limitations; (c) implement and follow procedures designed to ensure equitable treatment of each Fund; and (d) make quarterly reports to the Board of each Fund concerning any transactions by the applicable Fund under the InterFund Program and the InterFund Loan Rate charged.

12. The Advisers, through the InterFund Program Team, would administer the InterFund Program as disinterested fiduciaries as part of their duties under the investment management and administrative agreements with each Fund and would receive no additional fee as compensation for their services in connection with the administration of the InterFund Program. The Funds will bear transaction costs, including, without limitation, transaction, wire and other fees in connection with the facility, none of which would be paid to an Adviser. Such costs and fees would be no higher than those applicable for comparable bank loan transactions.

13. No Fund may participate in the InterFund Program unless: (a) The Fund has obtained shareholder approval for its participation, if such approval is required by law; (b) the Fund has fully disclosed all material information concerning the InterFund Program in its prospectus and/or statement of additional information; and (c) the Fund's participation in the InterFund Program is consistent with its investment objectives, investment restrictions, policies, limitations and organizational documents.

14. As part of the Board's review of the continuing appropriateness of a Fund's participation in the proposed InterFund Program as required by condition 14, the Board of the Fund, including a majority of the Independent Board Members, also will review the process in place to appropriately assess: (i) If the Fund participates as a lender, any effect its participation may have on the Fund's liquidity risk; and (ii) if the Fund participates as a borrower, whether the Fund's portfolio liquidity is sufficient to satisfy its obligations under the facility along with its other liquidity needs.

15. In connection with the InterFund Program, applicants request an order under section 6(c) of the Act exempting them from the provisions of sections 18(f) and 21(b) of the Act; under section 12(d)(1)(J) of the Act exempting them from section 12(d)(1) of the Act; under sections 6(c) and 17(b) of the Act exempting them from sections 17(a)(1), 17(a)(2), and 17(a)(3) of the Act; and under section 17(d) of the Act and rule 17d-1 under the Act to permit certain joint arrangements and transactions.

Applicants' Legal Analysis

1. Section 17(a)(3) of the Act generally prohibits any affiliated person of a registered investment company, or affiliated person of an affiliated person, from borrowing money or other property from the registered investment company. Section 21(b) of the Act generally prohibits any registered management company from lending money or other property to any person, directly or indirectly, if that person controls or is under common control with that company. Section 2(a)(3)(C) of the Act defines an "affiliated person" of another person, in part, to be any person directly or indirectly controlling, controlled by, or under common control with, such other person. Section 2(a)(9) of the Act defines "control" as the "power to exercise a controlling influence over the management or policies of a company," but excludes circumstances in which "such power is solely the result of an official position with such company." Applicants state that the Funds may be under common control by virtue of having common investment advisers and/or by having common trustees, directors, managers and/or officers.

2. Section 6(c) of the Act provides that an exemptive order may be granted where an exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Section 17(b) of the Act authorizes the Commission to exempt a proposed transaction from section 17(a) provided that the terms of the transaction, including the consideration to be paid or received, are fair and reasonable and do not involve overreaching on the part of any person

concerned, and the transaction is consistent with the policy of the investment company as recited in its registration statement and with the general purposes of the Act. Applicants believe that the proposed arrangements satisfy these standards for the reasons discussed below.

3. Applicants assert that sections 17(a)(3) and 21(b) of the Act were intended to prevent a party with strong potential adverse interests to, and some influence over the investment decisions of, a registered investment company from causing or inducing the investment company to engage in lending transactions that unfairly inure to the benefit of such party and that are detrimental to the best interests of the investment company and its shareholders. Applicants assert that the proposed transactions do not raise these concerns because: (a) The Advisers, through the InterFund Program Team members, would administer the InterFund Program as disinterested fiduciaries as part of their duties under the investment management and administrative agreements with each Fund; (b) all InterFund Loans would consist only of uninvested cash reserves that the Fund otherwise would invest in short-term repurchase agreements or other short-term investments; (c) the InterFund Loans would not involve a greater risk than such other investments; (d) the lending Fund would receive interest at a rate higher than it could otherwise obtain through short-term repurchase agreements or certain other short-term investments; and (e) the borrowing Fund would pay interest at a rate lower than otherwise available to it under its bank loan agreements. Moreover, applicants assert that the other terms and conditions that applicants propose also would effectively preclude the possibility of any Fund obtaining an undue advantage over any other Fund.

4. Section 17(a)(1) of the Act generally prohibits an affiliated person of a registered investment company, or any affiliated person of such a person, from selling securities or other property to the investment company. Section 17(a)(2) of the Act generally prohibits an affiliated person of a registered investment company, or any affiliated person of such a person, from purchasing securities or other property from the investment company. Section 12(d)(1) of the Act generally prohibits a registered investment company from purchasing or otherwise acquiring any security issued by any other investment company except in accordance with the limitations set forth in that section.

5. Applicants state that the obligation of a borrowing Fund to repay an InterFund Loan could be deemed to constitute a security for the purposes of sections 17(a)(1) and 12(d)(1). Applicants also state that any pledge of securities to secure an InterFund Loan by the borrowing Fund to the lending Fund could constitute a purchase of securities for purposes of section 17(a)(2) of the Act. Section 12(d)(1)(J) of the Act provides that the Commission may exempt persons or transactions from any provision of section 12(d)(1) if and to the extent that such exemption is consistent with the public interest and the protection of investors. Applicants submit that the requested exemptions meet the standards set forth in sections 6(c), 12(d)(1)(J) and 17(b) of the Act and rule 17d-1 under the Act. Applicants also state that the requested relief from section 17(a)(2) of the Act meets the standards of section 6(c) and 17(b) because any collateral pledged to secure an InterFund Loan would be subject to the same conditions imposed by any other lender to a Fund that imposes conditions on the quality of or access to collateral for a borrowing (if the lender is another Fund) or the same or better conditions (in any other circumstance).

6. Applicants state that section 12(d)(1) was intended to prevent the pyramiding of investment companies in order to avoid imposing on investors additional and duplicative costs and fees attendant upon multiple layers of investment companies. Applicants submit that the proposed InterFund Program does not involve these abuses. Applicants note that there will be no duplicative costs or fees to the Funds or their shareholders, and that each Adviser will receive no additional compensation for its services in administering the InterFund Program. Applicants also note that the purpose of the proposed InterFund Program is to provide economic benefits for all the participating Funds and their shareholders. Section 18(f)(1) of the Act prohibits open-end investment companies from issuing any senior security except that a company is permitted to borrow from any bank, provided, that immediately after the borrowing, there is asset coverage of at least 300 per centum for all borrowings of the company. Under section 18(g) of the Act, the term "senior security" generally includes any bond, debenture, note or similar obligation or instrument constituting a security and evidencing indebtedness. Applicants request exemptive relief under section 6(c) from section 18(f)(1) to the limited extent necessary to implement the InterFund Program (because the lending Funds are not banks).

7. Applicants believe that granting relief under section 6(c) is appropriate because the Funds would remain subject to the requirement of section 18(f)(1) that all borrowings of a Fund, including combined InterFund Loans and bank borrowings, have at least 300% asset coverage. Based on the conditions and safeguards described in the application, applicants also submit that to allow the Funds to borrow from other Funds pursuant to the proposed InterFund Program is consistent with the purposes and policies of section 18(f)(1).

8. Section 17(d) of the Act and rule 17d-1 under the Act generally prohibit an affiliated person of a registered investment company, or any affiliated person of such a person, when acting as principal, from effecting any joint transaction in which the investment company participates, unless, upon application, the transaction has been approved by the Commission. Rule 17d-1(b) under the Act provides that in passing upon an application filed under the rule, the Commission will consider whether the participation of the registered investment company in a joint enterprise, joint arrangement or profit sharing plan on the basis proposed is consistent with the provisions, policies and purposes of the Act and the extent to which such participation is on a basis different from or less advantageous than that of the other participants.

9. Applicants assert that the purpose of section 17(d) is to avoid overreaching by and unfair advantage to insiders. Applicants assert that the InterFund Program is consistent with the provisions, policies and purposes of the Act in that it offers both reduced borrowing costs and enhanced returns on loaned funds to all participating Funds and their shareholders. Applicants note that each Fund would have an equal opportunity to borrow and lend on equal terms consistent with its investment policies and fundamental investment limitations. Applicants assert that each Fund's participation in the proposed InterFund Program would be on terms that are no different from or less advantageous than that of other participating Funds.

Applicants' Conditions

Applicants agree that any order granting the requested relief will be subject to the following conditions:

1. The InterFund Loan Rate will be the average of the Repo Rate and the Bank Loan Rate.

2. On each business day when an interfund loan is to be made, the InterFund Program Team will compare the Bank Loan Rate with the Repo Rate and will make cash available for InterFund Loans only if the InterFund Loan Rate is: (a) More favorable to the lending Fund than the Repo Rate; and (b) more favorable to the borrowing Fund than the Bank Loan Rate.

3. If a Fund has outstanding bank borrowings, any InterFund Loan to the Fund will: (a) Be at an interest rate equal to or lower than the interest rate of any outstanding bank borrowing; (b) be secured at least on an equal priority basis with at least an equivalent percentage of collateral to loan value as any outstanding bank loan that requires collateral; (c) have a maturity no longer than any outstanding bank loan (and in any event not over seven days); and (d) provide that, if an event of default occurs under any agreement evidencing an outstanding bank loan to the Fund, that event of default by the Fund, will automatically (without need for action or notice by the lending Fund) constitute an immediate event of default under the interfund lending agreement which both (i) entitles the lending Fund to call the InterFund Loan immediately and exercise all rights with respect to any collateral and (ii) causes the call to be made if the lending bank exercises its right to call its loan under its agreement with the borrowing Fund.

4. A Fund may borrow on an unsecured basis through the InterFund Program only if the relevant borrowing Fund's outstanding borrowings from all sources immediately after the interfund borrowing total 10% or less of its total assets, provided that if the borrowing Fund has a secured loan outstanding from any other lender, including but not limited to another Fund, the lending Fund's InterFund Loan will be secured on at least an equal priority basis with at least an equivalent percentage of collateral to loan value as any outstanding loan that requires collateral. If a borrowing Fund's total outstanding borrowings immediately after an InterFund Loan would be greater than 10% of its total assets, the Fund may borrow through the InterFund Program only on a secured basis. A Fund may not borrow through the InterFund Program or from any other source if its total outstanding borrowings immediately after the borrowing would be more than 33⅓% of its total assets or any lower threshold provided for by the Fund's fundamental restriction or non-fundamental policy.

5. Before any Fund that has outstanding interfund borrowings may, through additional borrowings, cause its outstanding borrowings from all sources to exceed 10% of its total assets, it must first secure each outstanding InterFund Loan by the pledge of segregated collateral with a market value at least equal to 102% of the outstanding principal value of the loan. If the total outstanding borrowings of a Fund with outstanding InterFund Loans exceed 10% of its total assets for any other reason (such as a decline in net asset value or because of shareholder redemptions), the Fund will within one business day thereafter either: (a) Repay all its outstanding InterFund Loans; (b) reduce its outstanding indebtedness to 10% or less of its total assets; or (c) secure each outstanding InterFund Loan by the pledge of segregated collateral with a market value at least equal to 102% of the outstanding principal value of the loan until the Fund's total outstanding borrowings cease to exceed 10% of its total assets, at which time the collateral called for by this condition 5 shall no longer be required. Until each InterFund Loan that is outstanding at any time that a Fund's total outstanding borrowings exceed 10% of its total assets is repaid or the Fund's total outstanding borrowings cease to exceed 10% of its total assets, the Fund will mark the value of the collateral to market each day and will pledge such additional collateral as is necessary to maintain the market value of the collateral that secures each outstanding InterFund Loan at least equal to 102% of the outstanding principal value of the InterFund Loans.

6. No Fund may lend to another Fund through the InterFund Program if the loan would cause the lending Fund's aggregate outstanding loans through the InterFund Program to exceed 15% of its current net assets at the time of the loan.

7. A Fund's InterFund Loans to any one Fund shall not exceed 5% of the lending Fund's net assets.

8. The duration of InterFund Loans will be limited to the time required to receive payment for securities sold, but in no event more than seven days. Loans effected within seven days of each other will be treated as separate loan transactions for purposes of this condition.

9. A Fund's borrowings through the InterFund Program, as measured on the day when the most recent loan was made, will not exceed the greater of 125% of the Fund's total net cash redemptions for the preceding seven calendar days or 102% of the Fund's sales fails for the preceding seven calendar days.

10. Each InterFund Loan may be called on one business day's notice by a lending Fund and may be repaid on any day by a borrowing Fund.

11. A Fund's participation in the InterFund Program must be consistent with its investment restrictions, policies, limitations and organizational documents.

12. The InterFund Program Team will calculate total Fund borrowing and lending demand through the InterFund Program, and allocate InterFund Loans on an equitable basis among the Funds, without the intervention of any portfolio manager (other than a Money Market portfolio manager acting in his or her capacity as a member of the InterFund Program Team). All allocations will require the approval of at least one member of the InterFund Program Team who is high level employee and is not a Money Market portfolio manager. The InterFund Program Team will not solicit cash for the InterFund Program from any Fund or prospectively publish or disseminate loan demand data to portfolio managers (except to the extent that a Money Market portfolio manager has access to loan demand data). After the InterFund Program Team has allocated cash for InterFund Loans, any remaining cash will be invested in accordance with the standing instructions of the relevant portfolio manager or such remaining amounts will be invested directly by the portfolio managers of the Funds.

13. The InterFund Program Team will monitor the InterFund Loan Rate charged and the other terms and conditions of the InterFund Loans and will make a quarterly report to the Boards concerning the participation of the Funds in the InterFund Program and the terms and other conditions of any extensions of credit under the InterFund Program.

14. Each Board, including a majority of the Independent Board Members, will:

(a) Review, no less frequently than quarterly, the participation of each Fund it oversees in the InterFund Program during the preceding quarter for compliance with the conditions of any order permitting such participation;

(b) establish the Bank Loan Rate formula used to determine the interest rate on InterFund Loans;

(c) review, no less frequently than annually, the continuing appropriateness of the Bank Loan Rate formula; and

(d) review, no less frequently than annually, the continuing appropriateness of the participation in the InterFund Program by each Fund it oversees.

15. Each Fund will maintain and preserve for a period of not less than six

years from the end of the fiscal year in which any transaction by it under the InterFund Program occurred, the first two years in an easily accessible place, written records of all such transactions setting forth a description of the terms of the transaction, including the amount, the maturity and the InterFund Loan Rate, the rate of interest available at the time each InterFund Loan is made on overnight repurchase agreements and bank borrowings, and such other information presented to the Boards of the Funds in connection with the review required by conditions 13 and 14.

16. In the event an InterFund Loan is not paid according to its terms and the default is not cured within two business days from its maturity or from the time the lending Fund makes a demand for payment under the provisions of the interfund lending agreement, the Adviser to the lending Fund promptly will refer the loan for arbitration to an independent arbitrator selected by the Board of any Fund involved in the loan who will serve as arbitrator of disputes concerning InterFund Loans.[3] The arbitrator will resolve any problem promptly, and the arbitrator's decision will be binding on both Funds. The arbitrator will submit, at least annually, a written report to the Board of each Fund setting forth a description of the nature of any dispute and the actions taken by the Funds to resolve the dispute.

17. The Advisers will prepare and submit to the Board for review an initial report describing the operations of the InterFund Program and the procedures to be implemented to ensure that all Funds are treated fairly. After the commencement of the InterFund Program, the Advisers will report on the operations of the InterFund Program at each Board's quarterly meetings. Each Fund's chief compliance officer, as defined in rule 38a–1(a)(4) under the Act, shall prepare an annual report for its Board each year that the Fund participates in the InterFund Program, that evaluates the Fund's compliance with the terms and conditions of the application and the procedures established to achieve such compliance. Each Fund's chief compliance officer will also annually file a certification pursuant to Item 77Q3 of Form N–SAR as such Form may be revised, amended or superseded from time to time, for each year that the Fund participates in the InterFund Program, that certifies that the Fund and its Adviser have implemented procedures reasonably designed to achieve compliance with the terms and conditions of the order. In particular, such certification will address procedures designed to achieve the following objectives:

(a) That the InterFund Loan Rate will be higher than the Repo Rate but lower than the Bank Loan Rate;

(b) compliance with the collateral requirements as set forth in the application;

(c) compliance with the percentage limitations on interfund borrowing and lending;

(d) allocation of interfund borrowing and lending demand in an equitable manner and in accordance with procedures established by the Board; and

(e) that the InterFund Loan Rate does not exceed the interest rate on any third party borrowings of a borrowing Fund at the time of the InterFund Loan.

Additionally, each Fund's independent registered public accountants, in connection with their audit examination of the Fund, will review the operation of the InterFund Program for compliance with the conditions of the application and their review will form the basis, in part, of the auditor's report on internal accounting controls in Form N–SAR.

18. No Fund will participate in the InterFund Program, upon receipt of requisite regulatory approval, unless it has fully disclosed in its prospectus and/or statement of additional information all material facts about its intended participation.

For the Commission, by the Division of Investment Management, under delegated authority.

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–19184 Filed 8–11–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736.

Extension:

Rules 7a–15 through 7a–37, SEC File No. 270–115, OMB Control No. 3235–0132.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission ("Commission") has submitted to the Office of Management and Budget this request for extension of the previously approved collection of information discussed below.

Rules 7a–15 through 7a–37 (17 CFR 260.7a–15—260.7a–37) under the Trust Indenture Act of 1939 (15 U.S.C. 77aaa *et seq.*) set forth the general requirements as to form and content of applications, statements and reports that must be filed under the Trust Indenture Act. The respondents are persons and entities subject to the requirements of the Trust Indenture Act. Trust Indenture Act Rules 7a–15 through 7a–37 are disclosure guidelines and do not directly result in any collection of information. The rules are assigned only one burden hour for administrative convenience.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

The public may view the background documentation for this information collection at the following Web site, *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: August 5, 2016.

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–19183 Filed 8–11–16; 8:45 am]

BILLING CODE 8011–01–P

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[3] If the dispute involves Funds that do not have a common Board, the Board of each affected Fund will select an independent arbitrator that is satisfactory to each Fund.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78499; File No. SR–NYSEArca–2016–106]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Specify in Exchange Rules the Exchange's Use of Data Feeds From Investors' Exchange, LLC for Order Handling and Execution, Order Routing, and Regulatory Compliance

August 8, 2016.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the "Act")[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on July 26, 2016, NYSE Arca, Inc. (the "Exchange" or "NYSE Arca") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to specify in Exchange rules the Exchange's use of data feeds from Investors' Exchange, LLC for order handling and execution, order routing, and regulatory compliance. The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend NYSE Arca Equities Rule 7.37 ("Rule 7.37") and NYSE Arca Equities Rule 7.37P ("Rule 7.37P") to specify in Exchange rules which data feeds from Investors' Exchange, LLC ("IEX") that the Exchange would use for order handling and execution, order routing, and regulatory compliance.

On July 18, 2014, the Exchange filed a proposed rule change that clarified the Exchange's use of certain data feeds for order handling and execution, order routing, and regulatory compliance.[4] As noted in that filing, the data feeds available for the purposes of order handling and execution, order routing, and regulatory compliance at the Exchange include the exclusive securities information processor ("SIP") data feeds[5] or proprietary data feeds from individual market centers ("Direct Feed"). On February 24, 2015, the Exchange adopted Commentary .01 to Rule 7.37 to specify which data feeds that the Exchange uses for the handling, execution, and routing of orders, as well as for regulatory compliance.[6]

To reflect that IEX's application to register as a national securities exchange has been approved by the Commission[7] and that IEX intends to begin quoting and trading as a registered exchange on August 19, 2016, the Exchange proposes to amend Commentary .01 to Rule 7.37 and Rule 7.37P(d) to specify which data feeds the Exchange would use for IEX. As proposed, the Exchange would use the SIP Data Feed for IEX and would not have a secondary source.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[8] in general, and furthers the objectives of Section 6(b)(5),[9] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest. The Exchange believes that the proposed rule change removes impediments to and perfects the mechanism of a free and open market because it provides enhanced transparency to better assess the quality of an exchange's execution and routing services.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change is not designed to address any competitive issue but rather would provide the public and investors with information about which data feeds the Exchange uses for execution and routing decisions.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[10] and Rule 19b–4(f)(6) thereunder.[11] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[12]

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[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 72708 (July 29, 2014), 79 FR 45572 (Aug. 5, 2014) (SR–NYSEArca–2014–82).

[5] The SIP feeds are disseminated pursuant to effective joint-industry plans as required by Rule 603(b) of Regulation NMS. 17 CFR 242.603(b). The three joint-industry plans are: (1) The CTA Plan, which is operated by the Consolidated Tape Association and disseminates transaction information for securities with the primary listing market on exchanges other than NASDAQ Stock Market LLC ("Nasdaq"); (2) the CQ Plan, which disseminates consolidated quotation information for securities with their primary listing on exchanges other than Nasdaq; and (3) the Nasdaq UTP Plan, which disseminates consolidated transaction and quotation information for securities with their primary listing on Nasdaq.

[6] *See* Securities Exchange Act Release No. 74409 (March 2, 2015), 80 FR 12221 (March 6, 2015) (SR–NYSEArca–2015–11). Rule 7.37P, which is based on Rule 7.37, specifies order execution, including use of data feeds, on the Exchange's Pillar trading platform. *See* Securities Exchange Release No. 75494 (July 20, 2015), 80 FR 44170 (July 24, 2015) (SR–NYSEArca–2015–38).

[7] *See* Securities Exchange Act Release No. 78101 (June 17, 2016), 81 FR 41142 (June 23, 2016) (File No. 10–222).

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78s(b)(3)(A)(iii).

[11] 17 CFR 240.19b–4(f)(6).

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act [13] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii) [14] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange states that waiver of the 30-day operative delay would permit the Exchange to immediately enhance transparency and to accommodate the projected date that IEX will begin operating as a national securities exchange. Based on the foregoing, the Commission believes the waiver of the operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the operative delay and designates the proposal operative upon filing.[15]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File No. SR–NYSEArca–2016–106 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–NYSEArca–2016–106. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–NYSEArca–2016–106, and should be submitted on or before September 2, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–19177 Filed 8–11–16; 8:45 am]

BILLING CODE 8011–01–P

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[12] In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[13] 17 CFR 240.19b–4(f)(6).

[14] 17 CFR 240.19b–4(f)(6)(iii).

[15] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78503; File No. SR–CHX–2016–13]

Self-Regulatory Organizations; Chicago Stock Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Update or Adopt Various Fees for Services Provided by the Financial Industry Regulatory Authority

August 8, 2016

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 [2] thereunder, notice is hereby given that on August 4, 2016, the Chicago Stock Exchange, Inc. ("CHX" or the "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

CHX proposes to amend its Schedule of Fees and Assessments (the "Fee Schedule") to update or adopt various fees for services provided by the Financial Industry Regulatory Authority ("FINRA"). The text of this proposed rule change is available on the Exchange's Web site at (*www.chx.com*) and in the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the CHX included statements concerning the purpose of and basis for the proposed rule changes and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The CHX has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Section J.5 of the Fee Schedule to (1) update various current fees for examinations administered by FINRA and (2) adopt the Series 57 Securities Trader Examination fee,[3] so that such fees are identical to corresponding fees reflected under Section 4(c) of the Schedule A of the FINRA By-Laws. FINRA administers these programs on behalf of the exchanges and therefore the fees are payable directly to FINRA through the WebCRD.[4] Specifically, the Exchange proposes the following amendments:

- Amend the Series 7 Examination fee from $290 to $305.[5]
- Amend the Series 14 Examination fee from $335 to $350.[6]
- Amend the Series 27 Examination fee from $115 to $120.[7]
- Replace reference to the "Series 56 Examination" with the "Series 57 Examination" and adopt a corresponding fee of $120.[8]

Moreover, given that the Proprietary Trader Continuing Education program is no longer available,[9] the Exchange proposes to eliminate reference to the "Proprietary Trader Continuing Education (S501)" and the corresponding $60 fee.

The Exchange further proposes to add "Member Regulation" to the title of Section J of the CHX Fee Schedule, as the Exchange's Member Regulation department is responsible for ensuring that Participants comply with the relevant WebCRD fees, and "WebCRD" to the title of Section J.5 of the CHX Fee Schedule, as all fees under Section J.5 are paid directly to FINRA through the WebCRD, as noted above.

2. Statutory Basis

The Exchange believes that its proposal to amend its fee schedule is consistent with Section 6(b) of the Act[10] in general, and furthers the objectives of Section 6(b)(4) of the Act[11] in particular, in that it is an equitable allocation of reasonable dues, fees and other charges among Exchange members and issuers and other persons using its facilities. The Exchange believes that the proposal to adopt and update the various FINRA administered examination fees is an equitable allocation of dues, fees and other charges because the fee change applies equally to all Participants and the amended or adopted fees are identical to the corresponding fees charged by FINRA pursuant to Section 4(c) of the Schedule A of the FINRA By-Laws.

Moreover, the Exchange believes that harmonizing the FINRA administered examination fees with those of FINRA and the other national securities exchanges would further the objectives of Section 6(b)(5) of the Act[12] by removing impediments to and perfecting the mechanism of a free and open market and a national market system.

In addition, the Exchange believes that amending the title to Section J of the Fee Schedule to add the term "Member Regulation" would provide a complete description of the Exchange departments that are responsible for ensuring compliance with the fees set forth thereunder and amending the title to Section J.5 of the Fee Schedule clarifies that the fees set forth thereunder are paid directly to FINRA, which further the objectives of Section 6(b)(1) of the Act[13] in that it further enables the Exchange to be so organized as to have the capacity to be able to carry out the purposes of the Act and to comply, and to enforce compliance by its Participants and persons associated with its Participants, with the provisions of the Act, the rules and regulations thereunder, and the rules of the Exchange.

B. Self-Regulatory Organization's Statement of Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Given that the proposed fee change applies to all Participants and harmonizes the CHX Fee Schedule with corresponding fees charged by FINRA pursuant to Section 4(c) of the Schedule A of the FINRA By-Laws, the proposal has no effect on competition.

C. Self-Regulatory Organization's Statement on Comments Regarding the Proposed Rule Changes Received From Members, Participants or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)(ii) of the Act[14] and subparagraph(f)(2) of Rule 19b–4 thereunder[15] because it establishes or changes a due, fee or other charge imposed by the Exchange.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File No. SR–CHX–2016–13 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–CHX–2016–13. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the CHX. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–CHX–2016–13 and should be submitted on or before September 2, 2016.

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[3] The Exchange recently adopted the Securities Trader registration category and corresponding Series 57 Securities Trader Examination, which replaced the Proprietary Trader registration category and corresponding Series 56 Proprietary Examination requirement. *See* CHX Article 6, Rule 3(a); *see also* Securities Exchange Act Release No. 78445 (July 29, 2016) (SR–CHX–2016–11).

[4] WebCRD is the central licensing and registration system for the U.S. securities industry. The CRD system enables individuals and firms seeking registration with multiple states and self-regulatory organizations to do so by submitting a single form, fingerprint card and a combined payment of fees to FINRA. Through the CRD system, FINRA maintains the qualification, employment and disciplinary histories of registered associated persons of broker-dealers.

[5] *See* Section 4(c) of the Schedule A of the FINRA By-Laws.

[6] *Id.*

[7] *Id.*

[8] *Id.*

[9] *See* CHX Article 6, Rule 11(a)(3); *see also supra* note 3.

[10] 15 U.S.C. 78(f)(b).

[11] 15 U.S.C. 78(f)(b)(4).

[12] 15 U.S.C. 78(f)(b)(5).

[13] 15 U.S.C. 78f(b)(1).

[14] 15 U.S.C. 78s(b)(3)(A)(ii).

[15] 17 CFR 240.19b–4(f)(2).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–19172 Filed 8–11–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736.

Extension:

Form N–2; SEC File No. 270–21, OMB Control No. 3235–0026.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) the Securities and Exchange Commission (the "Commission") is soliciting comments on the collections of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget ("OMB") for extension and approval.

The title for the collection of information is "Form N–2 (17 CFR 239.14 and 274.11a–1) under the Securities Act of 1933 and under the Investment Company Act of 1940, Registration Statement of Closed-End Management Investment Companies." Form N–2 is the form used by closed-end management investment companies ("closed-end funds") to register as investment companies under the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.*) ("Investment Company Act") and to register their securities under the Securities Act of 1933 (15 U.S.C. 77a *et seq.*) ("Securities Act"). The primary purpose of the registration process is to provide disclosure of financial and other information current and potential investors for the purpose of evaluating an investment in a security. Form N–2 also permits closed-end funds to provide investors with a prospectus containing information required in a registration statement prior to the sale or at the time of confirmation of delivery of securities. The form also may be used by the Commission in its regulatory review, inspection, and policy-making roles.

The Commission estimates that there are 136 initial registration statements and 30 post-effective amendments to initial registration statements filed on Form N–2 annually and that the average number of portfolios referenced in each initial filing and post-effective amendment is 1. The Commission further estimates that the hour burden for preparing and filing an initial registration statement on Form N–2 is 515 hours per portfolio, and the hour burden for preparing and filing a post-effective amendment on Form N–2 is 107 hours per portfolio. The estimated annual hour burden for preparing and filing initial registration statements is 70,040 hours (136 initial registration statements × 1 portfolio × 515 hours per portfolio). The estimated annual hour burden for preparing and filing post-effective amendments is 3,210 hours (30 post-effective amendments × 1 portfolio × 107 hours per portfolio). The estimated total annual hour burden for Form N–2, therefore, is estimated to be 73,250 hours (70,040 hours + 3,210 hours).

The information collection requirements imposed by Form N–2 are mandatory. Responses to the collection of information will not be kept confidential. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid control number.

The public may view the background documentation for this information collection at the following Web site, *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: August 5, 2016.

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–19181 Filed 8–11–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78500; File No. SR–NYSEMKT–2016–72]

Self-Regulatory Organizations; NYSE MKT LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend NYSE MKT Rule 19—Equities To Specify in Exchange Rules the Exchange's Use of Data Feeds From Investors' Exchange, LLC for Order Handling and Execution, Order Routing, and Regulatory Compliance

August 8, 2016.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the "Act")[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on July 26, 2016, NYSE MKT LLC (the "Exchange" or "NYSE MKT") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

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[16] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend NYSE MKT Rule 19—Equities to specify in Exchange rules the Exchange's use of data feeds from Investors' Exchange, LLC for order handling and execution, order routing, and regulatory compliance. The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend NYSE MKT Rule 19—Equities ("Rule 19") to specify in Exchange rules which data feeds from Investors' Exchange, LLC ("IEX") that the Exchange would use for order handling and execution, order routing, and regulatory compliance.

On July 18, 2014, the Exchange filed a proposed rule change that clarified the Exchange's use of certain data feeds for order handling and execution, order routing, and regulatory compliance.[4] As noted in that filing, the data feeds available for the purposes of order handling and execution, order routing, and regulatory compliance at the Exchange include the exclusive securities information processor ("SIP") data feeds.[5] On February 24, 2015, the Exchange adopted Supplementary Material .01 to Rule 19 to specify which data feeds that the Exchange uses for the handling, execution, and routing of orders, as well as for regulatory compliance.[6]

To reflect that IEX's application to register as a national securities exchange has been approved by the Commission [7] and that IEX intends to begin quoting and trading as a registered exchange on August 19, 2016, the Exchange proposes to amend Supplementary Material .01 to Rule 19, to specify which data feeds the Exchange would use for IEX. As proposed, the Exchange would use the SIP Data Feed for IEX and would not have a secondary source.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[8] in general, and furthers the objectives of Section 6(b)(5),[9] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest. The Exchange believes that the proposed rule change removes impediments to and perfects the mechanism of a free and open market because it provides enhanced transparency to better assess the quality of an exchange's execution and routing services.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change is not designed to address any competitive issue but rather would provide the public and investors with information about which data feeds the Exchange uses for execution and routing decisions.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [10] and Rule 19b–4(f)(6) thereunder.[11] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[12]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act [13] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii) [14] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange states that waiver of the 30-day operative delay would permit the Exchange to immediately enhance transparency and to accommodate the projected date that IEX will begin operating as a national securities exchange. Based on the foregoing, the Commission believes the waiver of the operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the operative delay and designates the proposal operative upon filing.[15]

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[4] *See* Securities Exchange Act Release No. 72709 (July 29, 2014), 79 FR 45513 (Aug. 5, 2014) (SR–NYSEMKT–2014–62).

[5] The SIP feeds are disseminated pursuant to effective joint-industry plans as required by Rule 603(b) of Regulation NMS. 17 CFR 242.603(b). The three joint-industry plans are: (1) The CTA Plan, which is operated by the Consolidated Tape Association and disseminates transaction information for securities with the primary listing market on exchanges other than NASDAQ Stock Market LLC ("Nasdaq"); (2) the CQ Plan, which disseminates consolidated quotation information for securities with their primary listing on exchanges other than Nasdaq; and (3) the Nasdaq UTP Plan, which disseminates consolidated transaction and quotation information for securities with their primary listing on Nasdaq.

[6] *See* Securities Exchange Act Release No. 74408 (March 2, 2015), 80 FR (March 6, 2015) (SR–NYSEMKT–2015–11).

[7] *See* Securities Exchange Act Release No. 78101 (June 17, 2016), 81 FR 41142 (June 23, 2016) (File No. 10–222).

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78s(b)(3)(A)(iii).

[11] 17 CFR 240.19b–4(f)(6).

[12] In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[13] 17 CFR 240.19b–4(f)(6).

[14] 17 CFR 240.19b–4(f)(6)(iii).

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–NYSEMKT–2016–72 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–NYSEMKT–2016–72. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–NYSEMKT–2016–72, and should be submitted on or before September 2, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–19178 Filed 8–11–16; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78504; File No. SR–CHX–2016–14]

Self-Regulatory Organizations; Chicago Stock Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Continuing Education Fees

August 8, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 [2] thereunder, notice is hereby given that on August 1, 2016, the Chicago Stock Exchange, Inc. ("CHX" or the "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

CHX proposes to amend its Schedule of Fees and Assessments (the "Fee Schedule") to amend the Exchange's Continuing Education fees. The text of this proposed rule change is available on the Exchange's Web site at (*www.chx.com*) and in the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the CHX included statements concerning the purpose of and basis for the proposed rule changes and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The CHX has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On August 8, 2015, the Commission approved SR–FINRA–2015–015 relating to proposed changes to FINRA Rule 1250 to provide for Web-based delivery for completing the Regulatory Element of the Continuing Education requirements ("CE Online Program").[3] Moreover, as of July 1, 2016, FINRA required all participants to complete their Regulatory Element session using the CE Online Program; provided that participants who, pursuant to the Americans with Disabilities Act, need accommodations in completing their session due to a disability may apply for an accommodation and complete their session at a test center.[4] Pursuant to Section 4(f) of the Schedule A of the FINRA By-Laws, the fee for all Regulatory Element Continuing Education programs is $55.00.[5]

The Exchange currently utilizes the S101 General Program and S201 Supervisor Program that are part of the Securities Industry Continuing Education Program.[6] The Exchange recently filed a separate proposed rule change to adopt the changes set forth in SR–FINRA–2015–015 to provide for

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[15] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[16] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 75581 (July 31, 2015), 80 FR 47018 (August 6, 2015) (Order Approving a Proposed Rule Change to Provide a Web-based Delivery Method for Completing the Regulatory Element of the Continuing Education Requirements) (SR–FINRA–2015–015).

[4] *See* Securities Exchange Act Release No. 78281 (July 11, 2016), 81 FR 46133 (July 15, 2016) (SR–FINRA–2016–025); *see also* Americans with Disabilities Act of 1990, Public Law 101–336, 104 Stat. 328 (1990).

[5] *See id.*

[6] The Securities Industry/Regulatory Council on Continuing Education has advisory and consultative responsibilities with regard to the development, implementation and ongoing operation of the Securities Industry Continuing Education Program.

Web-based delivery of the Regulatory Element of the Continuing Education programs.[7]

Consistent with Section 4(f) of the Schedule A of the FINRA By-Laws, the Exchange now proposes to amend Section J.5 of the CHX Fee Schedule to provide that the Continuing Education Regulatory Element fee for the S101 and S201 programs will be $55.[8]

2. Statutory Basis

The Exchange believes that its proposal to amend its fee schedule is consistent with Section 6(b) of the Act[9] in general, and furthers the objectives of Section 6(b)(4) of the Act[10] in particular, in that it is an equitable allocation of reasonable dues, fees and other charges among Exchange members and issuers and other persons using its facilities. The Exchange believes that the proposal to set the Continuing Education fee at $55 is an equitable allocation of dues, fees and other charges because the fee change applies equally to all persons associated with Participants. In addition, the Exchange believes that the amended fee is an equitable allocation of dues, fees and other charges as it will apply uniformly to all persons associated with the Participants who participate in the continuing education program through FINRA.

Moreover, the Exchange believes that harmonizing the Continuing Education fee with those of FINRA and the other national securities exchanges would further the objectives of Section 6(b)(5) of the Act[11] by removing impediments to and perfecting the mechanism of a free and open market and a national market system.

B. Self-Regulatory Organization's Statement of Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. Since the proposed rule change applies to all persons associated with Participants who are required to fulfill Continuing Education requirements, the proposal has no effect on competition. Moreover, the Exchange believes that the harmonization of the Continuing Education fee across the various markets will reduce burdens on competition by removing impediments to participation in the national market system.

C. Self-Regulatory Organization's Statement on Comments Regarding the Proposed Rule Change Received From Members, Participants or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)(ii) of the Act[12] and subparagraph(f)(2) of Rule 19b–4 thereunder[13] because it establishes or changes a due, fee or other charge imposed by the Exchange.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–CHX–2016–14 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–CHX–2016–14. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the CHX. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–CHX–2016–14 and should be submitted on or before September 2, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–19173 Filed 8–11–16; 8:45 am]

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[7] CHX Article 6, Rule 11(a)(4) provides that the continuing education Regulatory Element will be administered through Web-based delivery or such other technological manner and format as specified by the Exchange. *See* Securities Exchange Act Release No. 78446 (July 29, 2016) (SR–CHX–2016–12).

[8] Section J.5 of the CHX Fee Schedule provides that the Continuing Education fees are paid to FINRA directly. This fee is currently $100.00 for each individual who is required to complete the S101 or S201 programs.

[9] 15 U.S.C. 78(f)(b).

[10] 15 U.S.C. 78(f)(b)(4).

[11] 15 U.S.C. 78(f)(b)(5).

[12] 15 U.S.C. 78s(b)(3)(A)(ii).

[13] 17 CFR 240.19b–4(f)(2).

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78497; File No. SR–NYSEARCA–2016–110]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Section 3 of NYSE Arca Equities Rule 8 To Extend the Effectiveness of the Exchange Traded Product Incentive Program

August 8, 2016.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the "Act")[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on July 28, 2016, NYSE Arca, Inc. (the "Exchange" or "NYSE Arca") filed with the

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[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Section 3 of NYSE Arca Equities Rule 8 (Trading of Certain Equity Derivatives) to extend the effectiveness of the Exchange Traded Product ("ETP") Incentive Program until July 31, 2017. The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Section 3 of NYSE Arca Equities Rule 8 (Trading of Certain Equity Derivatives) to extend the effectiveness of the ETP Incentive Program[4] until July 31, 2017.[5]

The ETP Incentive Program is a pilot program designed to incentivize quoting and trading in ETPs and to add competition among existing qualified Market Makers.[6] In addition, the ETP Incentive Program is designed to enhance the market quality for ETPs by incentivizing Market Makers to take LMM[7] assignments in certain lower-volume ETPs by offering an alternative fee structure for such LMMs that would be funded from the Exchange's general revenues. The ETP Incentive Program is designed to improve the quality of market for lower-volume ETPs, thereby incentivizing issuers to list them on the Exchange. Moreover, as described in the ETP Incentive Program Release, the Exchange believes that the ETP Incentive Program, which is entirely voluntary, encourages competition among markets for issuers' listings and among Market Makers for LMM assignments.

The Exchange proposes to extend the current operation of the ETP Incentive Program until July 31, 2017 to allow the Commission, the Exchange, LMMs, and issuers to further assess the impact of such program before proposing to make it available to other securities and implementing the program on a permanent basis.[8] Issuers began participating in the ETP Incentive Program following the extension of the first pilot period. The Exchange believes that extending the ETP Incentive Program pilot period for an additional approximately eleven months will provide additional time to assess the impact of the program for these issuers and to provide time for additional issuers to participate in the ETP Incentive Program so that the Commission, the Exchange, LMMs, and issuers may assess the impact of the program before making it available to other securities or implementing it on a permanent basis.[9]

In accordance with the 2015 Extension Notice, the Exchange, on April 4, 2016, posted on its Web site an "Assessment Report" regarding the ETP

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[4] The Commission approved the ETP Incentive Program on a pilot basis in Securities Exchange Act Release No. 69706 (June 6, 2013), 78 FR 35340 (June 12, 2013) (SR–NYSEArca-2013–34) ("ETP Incentive Program Release"). The Exchange subsequently filed to extend the original pilot program for the ETP Incentive Program until September 4, 2015. *See* Securities Exchange Act Release No. 72963 (September 3, 2014), 79 FR 53492 (September 9, 2014) (SR–NYSEArca–2014–99) (notice of filing and immediate effectiveness of proposed rule change extending effectiveness of the ETP Incentive Program until September 4, 2015). Most recently, the Exchange filed to extend the pilot program for the ETP Incentive Program until September 4, 2016 (*See* Securities Exchange Act Release No. 75846 (September 4, 2015), 80 FR 54646 (September 10, 2015) (SR–NYSEArca–2015–78) (notice of filing and immediate effectiveness of proposed rule change extending effectiveness of the ETP Incentive Program until September 4, 2016) ("2015 Extension Notice"). In addition, the Exchange filed a proposed rule change to amend Rules 7.25(c) and 8.800(b) to provide that exchange-traded products ("ETPs") already listed on the Exchange can be admitted to the ETP Incentive Program on a monthly basis rather than at the beginning of each quarter. *See* Securities Exchange Act Release No. 75282 (June 24, 2015), 80 FR 37340 (June 30, 2015) (SR–NYSEArca–2015–52) (notice of filing and immediate effectiveness of proposed rule change amending NYSE Arca Equities Rules 7.25 and 8.800 to allow an issuer to elect for its ETP to participate in the Crowd Participant Program or the ETP Incentive Program monthly rather than quarterly and to extend the effectiveness of the Crowd Participant Program until June 23, 2016). In SR–NYSEArca–2015–52, the Exchange stated that the Exchange anticipates that expanding the opportunity for issuers to enter the ETP Incentive Program will facilitate the provision of extra liquidity to lower-volume ETPs by incentivizing more Market Makers to take Lead Market Maker ("LMM") assignments in certain lower-volume ETPs.

[5] The ETP Incentive Program is scheduled to end on September 4, 2016. For purposes of the ETP Incentive Program, ETPs include securities listed on the Exchange under the following rules: NYSE Arca Equities Rules 5.2(j)(3) (Investment Company Units), 5.2(j)(5) (Equity Gold Shares), 8.100 (Portfolio Depositary Receipts), 8.200 (Trust Issued Receipts), 8.201 (Commodity-Based Trust Shares), 8.202 (Currency Trust Shares), 8.203 (Commodity Index Trust Shares), 8.204 (Commodity Futures Trust Shares), 8.300 (Partnership Units), 8.600 (Managed Fund Shares), and 8.700 (Managed Trust Securities).

[6] A Market Maker is an Equity Trading Permit Holder that acts as a Market Maker pursuant to NYSE Arca Equities Rule 7. *See* NYSE Arca Equities Rule 1.1(v). An Equity Trading Permit Holder is a sole proprietorship, partnership, corporation, limited liability company, or other organization in good standing that has been issued an Equity Trading Permit. *See* NYSE Arca Equities Rule 1.1(n).

[7] The LMM program is designed to incentivize firms to take on the LMM designation and foster liquidity provision and stability in the market. In order to accomplish this, the Exchange currently provides LMMs with an opportunity to receive incrementally higher transaction credits and incur incrementally lower transaction fees ("LMM Rates") compared to standard liquidity maker-taker rates ("Standard Rates"). The Exchange generally employs a maker-taker transactional fee structure, whereby an Equity Trading Permit Holder that removes liquidity is charged a fee ("Take Rate"), and an Equity Trading Permit Holder that provides liquidity receives a credit ("Make Rate"). *See* Trading Fee Schedule, available at *https://www.nyse.com/publicdocs/nyse/markets/nyse-arca/NYSE_Arca_Marketplace_Fees.pdf.*

[8] The Exchange notes that any proposed further continuance of the ETP Incentive Program, a proposal to make the ETP Incentive Program permanent, or a proposal to make such program available to other securities would require a rule filing with the Commission pursuant to Section 19(b) of the Act and Rule 19b–4 thereunder.

[9] The Exchange has provided to the Commission monthly market quality reports relating to the ETP Incentive Program for the period October 2014 through June 2016, which are posted to the Exchange's Web site at *https://www.nyse.com/products/etp-incentive-program.*

Incentive Program.[10] The Assessment Report examined the performance of the ETPs in the Incentive Program during the entire period in which they were in the program, and provided statistical analyses with respect to the following factors: volume (consolidated average daily volume ("CADV") and NYSE Arca average daily volume); national best bid and offer ("NBBO") bid/ask spread differential; LMM participation rates; NYSE Arca market share; LMM time spent at the inside; LMM time spent within $0.03 of the inside; percentage of time NYSE Arca had the best price with the best size; LMM quoted spread; and LMM quoted depth. The Assessment Report assessed whether the ETP Incentive Program has met its proposed goals to incentivize market makers to take LMM assignments in certain lower-volume ETPs. The Assessment Report concluded that, while the results in certain cases show strong evidence of higher market quality in some ETPs based on participation in the ETP Incentive Program, the data is less conclusive for other ETPs due, in large part to the limited data available. In addition, a number of variables impact the ability to assess the limited data described in the Assessment Report, including market conditions, product variability, and product inception date. Therefore, the Assessment Report concluded that it is difficult to state conclusively whether the Incentive Program has met its objectives. Consistent with the conclusions of the Assessment Report, the Exchange believes that the Incentive Program should continue as a pilot program for an additional approximately eleven months in order to provide more time for participation so that the Exchange, the Commission, and market participants can meaningfully assess whether the Incentive Program will meet its proposed goals.

Prior to the end of the pilot period ending July 31, 2017, the Exchange will post a report relating to the ETP Incentive Program (the "Assessment Report") on its Web site three months before the end of the pilot period or at the time it files to terminate the pilot, whichever comes first. The proposed Assessment Report would list the program objectives that are the focus of the pilot and, for each, provide (a) a statistical analysis that includes evidence that is sufficient to inform a reader about whether the program has met those objectives during the pilot period, along with (b) a narrative explanation of whether and how the evidence indicates the pilot has met the objective, including both strengths and weaknesses of the evidence in this regard. The Assessment Report also would include a discussion of (a) the procedures used in selecting any samples that are used in constructing tables or statistics for inclusion in the Assessment Report, (b) the definitions of any variables and statistics reported in the tables, including test statistics, (c) the statistical significance levels of any test statistics and (d) other statistical or qualitative information that may enhance the usefulness of the Assessment Report as a basis for evaluating the performance of the program. The Assessment Report would present statistics on product performance relative to the performance of comparable or other suitable benchmark products (including test statistics that permit the reader to evaluate the statistical significance of any differences reported or discussed in the report), along with information on the procedures that were used to identify those comparable or benchmark products, the characteristics of each comparable or benchmark products, the characteristics of each product that is the focus of the pilot, the procedures used in selecting the time horizon of the sample and the sensitivity of reported statistics to changes in the time horizon of the sample.

This filing is not otherwise intended to address any other issues and the Exchange is not aware of any problems that Equity Trading Permit Holders or issuers would have in complying with the monthly selection provision or the proposed extension of the pilot program.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[11] in general, and furthers the objectives of Section 6(b)(5) of the Act,[12] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Exchange believes that the ETP Incentive Program is designed to enhance the market quality for ETPs by incentivizing Market Makers to take LMM assignments in certain lower volume ETPs by offering an alternative fee structure for such LMMs that would be funded from the Exchange's general revenues. The ETP Incentive Program is designed to improve the quality of market for lower-volume ETPs, thereby incentivizing them to list on the Exchange. Moreover, as described in the ETP Incentive Program Release, the Exchange believes that the ETP Incentive Program, which is entirely voluntary, encourages competition among markets for issuers' listings and among Market Makers for LMM assignments.

The Exchange believes that, by providing additional time for issuers to participate in the ETP Incentive Program, through an extension of the pilot period until July 31, 2017, the ETP Incentive Program would continue to provide an opportunity for rewarding competitive liquidity-providing LMMs, with associated requirements for quoting by LMMs at the National Best Bid or National Best Offer. The ETP Incentive Program, therefore, has the potential to enhance competition among liquidity providers and thereby improve execution quality on the Exchange. An extension of such pilot period will permit additional time to collect data on the ETP Incentive Program so that the Commission, the Exchange, LMMs, and issuers may assess the impact of the ETP Incentive Program before making it available to other securities. The Exchange will continue to monitor the efficacy of the ETP Incentive Program during the extended pilot period. Prior to the end of the pilot period ending July 31, 2017, the Exchange proposes to post an Assessment Report on its Web site three months before the end of the pilot period or at the time it files to terminate the pilot, whichever comes first. The proposed Assessment Report would list the program objectives that are the focus of the pilot as well as additional information described above.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The proposed extension to the pilot period for the ETP Incentive Program is not designed to address any competitive issues but rather to program additional time for the Commission, the Exchange, LMMs and issuers to assess the impact of such program.

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[10] The Assessment Report is available at *https://www.nyse.com/publicdocs/nyse/products/etp-funds/ETP_Incentive_Program_Assessment_Report.pdf.*

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[13] and Rule 19b–4(f)(6) thereunder.[14] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.

A proposed rule change filed under Rule 19b–4(f)(6)[15] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b4(f)(6)(iii),[16] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[17] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSEARCA–2016–110 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEARCA–2016–110. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEARCA–2016–110 and should be submitted on or before September 2, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–19175 Filed 8–11–16; 8:45 am]

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[13] 15 U.S.C. 78s(b)(3)(A)(iii).

[14] 17 CFR 240.19b–4(f)(6).

[15] 17 CFR 240.19b–4(f)(6).

[16] 17 CFR 240.19b–4(f)(6)(iii).

[17] 15 U.S.C. 78s(b)(2)(B).

[18] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78505; File No. SR–MIAX–2016–23]

Self-Regulatory Organizations; Miami International Securities Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fee Schedule

August 8, 2016

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 1, 2016, Miami International Securities Exchange LLC ("MIAX" or "Exchange") filed with the Securities and Exchange Commission ("Commission") a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend the MIAX Options Fee Schedule ("Fee Schedule") to eliminate certain Web CRD Fees in order to address the transition of the Regulatory Element of Continuing Education ("CE") to the FINRA CE Online System®.

The text of the proposed rule change is available on the Exchange's Web site at *http://www.miaxoptions.com/filter/wotitle/rule_filing,* at MIAX's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend Section 2(c) of the Regulatory Fees section of the Fee Schedule, Web CRD Fees, to (1) delete the $100 Continuing Education Fee for All Registrations, which relates to test center delivery of the Regulatory Element of CE, and (2) clarify that the $55 Continuing Education Fee for All Registrations if Web-based shall apply to all registrations without regard to mode of session delivery.

Specifically, the Exchange proposes to (1) delete the $100 CE Fee in its entirety, and (2) with respect to the $55 CE Fee, delete reference to Web-based delivery and specify that it is a "session" fee.

MIAX is proposing such Fee Schedule amendments in conjunction with FINRA's transition to CE Online and its phase out of test center delivery of the CE Regulatory Element.[3]

Background

On July 31, 2015, the Commission approved [sic] SR–FINRA–2015–015 relating to proposed changes to FINRA Rules to provide for Web-based delivery completion of the Regulatory Element of CE requirements. Pursuant to the rule change, the Regulatory Element of CE programs is administered through Web-based delivery via the FINRA CE Online System as of January 4, 2016. Pursuant to the rule change, the Regulatory Element of CE programs also continued to be offered at test centers until no later than six months after January 4, 2016. Test-center delivery of the Regulatory Element has been phased out effective July 1, 2016.[4] On July 11, 2016, the Commission approved SR–FINRA–2016–025 relating to proposed changes to FINRA Fees for the Regulatory Element of CE.

In January 2016 the Exchange amended its Rules,[5] in consultation with FINRA and the other exchanges, to provide for Web-based delivery of the CE Regulatory Element for registered persons.

Proposal

The Exchange now proposes to amend its Fee Schedule to delete the $100 CE Fee for All Registrations since the test center delivery option for the Regulatory Element will no longer be offered[6] and the $100 fee currently charged for administration of non-Web-based CE programs is therefore retired.[7] Therefore, the Exchange proposes to delete this fee from its current Fee Schedule.

The Exchange further proposes to clarify that the $55 CE Fee will now generally apply to all CE sessions without further specifying the Web-based delivery mode since there will no longer be more than one mode of CE delivery.[8] Therefore, the Exchange proposes to delete the reference to Web-based delivery from Section 2(c) of the Fee Schedule and specify that it is a "session" fee in order to provide clarity and avoid confusion.

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act[9] in general, and furthers the objectives of Section 6(b)(4) of the Act[10] in particular, in that it is an equitable allocation of reasonable fees and other charges among Exchange members and issuers and other persons using its facilities.

The Exchange believes that the proposal is fair, equitable and not unreasonably discriminatory because the fee change applies equally to all Members and persons associated with Members. The Exchange believes that the proposal is reasonable because FINRA will administer the CE program only through the FINRA CE Online System and will no longer offer a testing center CE delivery option, except as specifically noted above in which case FINRA has aligned its $55 session fee for all participants.[11] In addition, the Exchange believes this session fee is equitable and not unfairly discriminatory as it will apply uniformly to all Members and persons associated with the Members who choose to participate in the CE program provided through FINRA.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange further believes that the proposal does not impose any burden on competition because FINRA has made, and the Exchange believes that the other exchanges will make, similar changes to their fee schedules.[12]

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[13] and Rule 19b–4(f)(2)[14] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

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[3] *See* Securities Exchange Act Release No. 78281 (July 11, 2016), 81 FR 46133 (July 15, 2016) (SR–FINRA–2016–025) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to the Fee for the Regulatory Element of Continuing Education). *See also* Securities Exchange Act Release No. 75581 (July 31, 2015), 80 FR 47018 (August 6, 2015) (SR–FINRA–2015–015) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Provide a Web-based Delivery Method for Completing the Regulatory Element of the Continuing Education Requirements), *Regulatory Notice* 15–28 (August 2015) and *Information Notice,* May 16, 2016 (Elimination of Continuing Education Delivery at Testing Centers).

[4] *See Information Notice,* May 16, 2016 (Elimination of Continuing Education Delivery at Testing Centers). Notwithstanding such test center phase out, participants who may need accommodations in completing their CE session due to a disability pursuant to the Americans with Disabilities Act of 1990, Public Law 101–336, 104 Stat. 328 (1990) ("ADA") may apply for an accommodation and complete their CE Regulatory Element session at a test center. *See* FINRA's CE Online Delivery Accommodation Web page, available at *http://www.finra.org/industry/accommodations-continuing-education-ce-online-participants.*

[5] *See* Securities Exchange Act Release No. 76892 (January 13, 2016), 81 FR 3206 (January 20, 2016) (SR–MIAX–2016–01).

[6] *See supra* note 4.

[7] *See* Securities Exchange Act Release No. 78281 (July 11, 2016), 81 FR 46133 (July 15, 2016) (SR–FINRA–2016–025) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to the Fee for the Regulatory Element of Continuing Education).

[8] With the exception of participants who may need accommodations in completing their CE session due to a disability pursuant to the ADA and to whom the session fee of $55 for the Regulatory Element shall apply regardless of whether the session is completed at a test center or through the CE Online System. *See* Securities Exchange Act Release No. 78281 (July 11, 2016), 81 FR 46133 (July 15, 2016) (SR- FINRA–2016–025) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to the Fee for the Regulatory Element of Continuing Education).

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(4).

[11] *See supra* note 7.

[12] *See id.*

[13] 15 U.S.C. 78s(b)(3)(A)(ii).

[14] 17 CFR 240.19b–4(f)(2).

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–MIAX–2016–23 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–MIAX–2016–23. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the MIAX. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–MIAX–2016–23 and should be submitted on or before September 2, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–19174 Filed 8–11–16; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copy Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736.

Extension:

Rule 0–4, SEC File No. 270–569, OMB Control No. 3235–0633.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the "Commission") is soliciting comments on the collection of information summarized below. The Commission plans to submit this collection of information to the Office of Management and Budget for extension and approval.

Rule 0–4 (17 CFR 275.0–4) under the Investment Advisers Act of 1940 ("Act" or "Advisers Act") (15 U.S.C. 80b–1 *et seq.*) entitled "General Requirements of Papers and Applications," prescribes general instructions for filing an application seeking exemptive relief with the Commission. Rule 0–4 currently requires that every application for an order for which a form is not specifically prescribed and which is executed by a corporation, partnership or other company and filed with the Commission contain a statement of the applicable provisions of the articles of incorporation, bylaws or similar documents, relating to the right of the person signing and filing such application to take such action on behalf of the applicant, and a statement that all such requirements have been complied with and that the person signing and filing the application is fully authorized to do so. If such authorization is dependent on resolutions of stockholders, directors, or other bodies, such resolutions must be attached as an exhibit to or quoted in the application. Any amendment to the application must contain a similar statement as to the applicability of the original statement of authorization. When any application or amendment is signed by an agent or attorney, rule 0–4 requires that the power of attorney evidencing his authority to sign shall state the basis for the agent's authority and shall be filed with the Commission. Every application subject to rule 0–4 must be verified by the person executing the application by providing a notarized signature in substantially the form specified in the rule. Each application subject to rule 0–4 must state the reasons why the applicant is deemed to be entitled to the action requested with a reference to the provisions of the Act and rules thereunder, the name and address of each applicant, and the name and address of any person to whom any questions regarding the application should be directed. Rule 0–4 requires that a proposed notice of the proceeding initiated by the filing of the application accompany each application as an exhibit and, if necessary, be modified to reflect any amendment to the application.

The requirements of rule 0–4 are designed to provide Commission staff with the necessary information to assess whether granting the orders of exemption are necessary and appropriate in the public interest and consistent with the protection of investors and the intended purposes of the Act.

Applicants for orders under the Advisers Act can include registered investment advisers, affiliated persons of registered investment advisers, and entities seeking to avoid investment adviser status, among others. Commission staff estimates that it receives up to 3 applications per year submitted under rule 0–4 of the Act seeking relief from various provisions of the Advisers Act and, in addition, up to 9 applications per year submitted under Advisers Act rule 206(4)–5, which addresses certain "pay to play" practices and also provides the Commission the authority to grant applications seeking relief from certain of the rule's restrictions. Although each application typically is submitted on behalf of multiple applicants, the applicants in the vast majority of cases are related entities and are treated as a single respondent for purposes of this analysis. Most of the work of preparing an application is performed by outside counsel and, therefore, imposes no hourly burden on respondents. The cost outside counsel charges applicants depends on the complexity of the issues covered by the application and the time required. Based on conversations with applicants and attorneys, the cost for applications ranges from approximately $12,800 for preparing a well-precedent, routine (or otherwise less involved) application to approximately $200,000 to prepare a complex or novel application. We estimate that the Commission receives 1 of the most time-consuming applications annually, 2 applications of medium difficulty, and 9 of the least difficult applications subject to rule 0–4.[1] This distribution gives a total estimated annual cost burden to applicants of filing all applications of $402,200 [(1 × $200,000) + (2 × $43,500) + (9 × $12,800)]. The estimate of annual cost burden is made solely for the purposes of the Paperwork Reduction Act, and is not derived from a comprehensive or even representative survey or study of the costs of Commission rules and forms.

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[15] 17 CFR 200.30–3(a)(12).

The requirements of this collection of information are required to obtain or retain benefits. Responses will not be kept confidential. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid control number.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to Pamela Dyson, Chief Information Officer, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549; or send an email to: *PRA_Mailbox@sec.gov.*

Dated: August 9, 2016.

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–19207 Filed 8–11–16; 8:45 am]

BILLING CODE 8011–01–P

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[1] The estimated 9 least difficult applications include the estimated 9 applications per year submitted under Advisers Act rule 206(4)–5.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78501; File No. SR–ICC–2016–007]

Self-Regulatory Organizations; ICE Clear Credit LLC; Order Approving Proposed Rule Change To Revise the ICC End-of-Day Price Discovery Policies and Procedures

August 8, 2016

I. Introduction

On April 22, 2016, ICE Clear Credit LLC ("ICC") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act ("Act")[1] and Rule 19b–4 thereunder,[2] a proposed rule change relating to ICC's End-of-Day Price Discovery Policies and Procedures (the "EOD Policy"). The proposed rule change was published for comment in the **Federal Register** on May 11, 2016.[3] On June 23, 2016, the Commission extended the time period in which to either approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change to August 9, 2016.[4] The Commission did not receive comments on the proposed rule change. For the reasons discussed below, the Commission is approving the proposed rule change.

II. Description of the Proposed Rule Change

The principal purpose of the proposed rule change is to revise the EOD Policy to change the calculation of single name firm trade ("Firm Trade") notional limits to be at a Clearing Participant ("CP") affiliate group level.

As part of ICC's end-of-day price discovery process, ICC CPs are required to submit end-of-day prices for specific instruments related to their open interest at ICC. ICC determines end-of-day levels directly from these CP price submissions using a proprietary algorithm. To encourage CPs to provide high quality end-of-day submissions, on random days, ICC selects a subset of instruments which are eligible for Firm Trades. In order to determine Firm Trade requirements, the algorithm sorts and ranks all CP submissions and identifies "crossed and/or locked markets." Crossed markets are pairs of CP submitted prices generated by the sorting and ranking process for which the bid price of one CP is above the offer price of the matched CP. The algorithm identifies locked markets, where the bid and the offer are equal, in a similar fashion.

ICC designates certain crossed and/or locked markets as Firm Trades and CPs are entered into cleared transactions. ICC establishes pre-defined notional amounts for Firm Trades. According to ICC, no single Firm Trade can have a larger notional amount than specified by the pre-defined notional amount for the relevant instrument. On a given Firm Trade day, all potential-trades resulting from the cross-and-lock algorithm in any Firm Trade eligible instrument are designated Firm Trades, unless they breach a CP's notional limits.

Currently single name Firm Trade notional limits are set at the CP level. According to ICC, it designed the Firm Trade system to incentivize trading desks to provide quality end-of-day price submissions for use in its end-of-day price discovery process, while limiting the total overnight risk that a given institution may be required to manage in case of submission errors or outlying pricing submissions which may lead to Firm Trades. One mechanism introduced to provide these protections was single name Firm Trade notional limits per CP. ICC believes that at the time of its introduction, this mechanism achieved its goal of limiting overnight risk limits per institution. However, with the increase in client clearing and in multiple CP memberships per holding company, ICC asserts that the limit provided to a given institution is multiples of that originally contemplated.

In addition, because of recent changes to the EOD Policy to extend the process for determining Firm Trades to include all submissions, including those classified as outlying pricing submissions (or "obvious errors"),[5] ICC asserts that CPs are eligible to receive Firm Trades on a wider range of price submissions. Due to the broadened scope of the Firm Trade process, ICC asserts a heightened interest in adjusting the allocation process so that CPs are not over-penalized for Firm Trades in terms of overnight risk exposure.

In order to maintain the original intent of the end-of-day price discovery process, ICC has proposed changes to its EOD Policy to implement single name Firm Trade notional limits at the CP affiliate group level, as opposed to the

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 34–77771 (May 5, 2016), 81 FR 29309 (May 11, 2016) (SR–ICC–2016–007).

[4] Securities Exchange Act Release No. 34–78144 (June 23, 2016), 81 FR 42018 (June 28, 2016) (SR–ICC–2016–007).

[5] *See* Securities Exchange Act Release No. 34–74053 (January 14, 2015), 80 FR 2985 (January 21, 2015) (SR–ICC–2015–001).

CP level. ICC represents that the proposed changes will return the process to its original design and limit the total overnight risk that a given institution may be required to manage in the case of submission errors or outlying pricing submissions which may lead to Firm Trades.

A "CP affiliate group" will be defined as the set of all affiliated CPs (*i.e.* any CPs that own, are owned by, or are under common ownership with another CP). According to ICC, as the sequence of crosses is considered, the executed single name Firm Trade notional value will be tracked for all CPs in a CP affiliate group. ICC states that no additional single name Firm Trades will be executed against any CP in a CP affiliate group once the CP affiliate group notional limit for single name Firm Trades is reached. ICC asserts there are no changes to the Firm Trade algorithm as a result of these changes. ICC further asserts that setting single name Firm Trade notional limits on an affiliate group basis is consistent with price submission practices where end-of-day submissions from multiple affiliated entities often reflect the institution's overall view on the market.

ICC states that the proposal returns single name Firm Trade notional limits to the original design while maintaining the system's price submission incentives. ICC represents that all CPs within an affiliate group will still be subject to potential Firm Trades for any given submission, on a randomized basis. ICC also asserts that though Firm Trade notional limits will be implemented at the CP affiliate group level, the potential implication for a given trading desk of providing an off-market submission for a given instrument remains the same. ICC believes there will be no change in price submission behavior as a result of the changes, and the Firm Trade process will remain an effective tool for ensuring quality price submissions.

III. Discussion and Commission Findings

Section 19(b)(2)(C) of the Act[6] directs the Commission to approve a proposed rule change of a self-regulatory organization if the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to such self-regulatory organization. Section 17A(b)(3)(F) of the Act[7] requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions, and to the extent applicable, derivative agreements, contracts and transactions, to assure the safeguarding of securities and funds which are in the custody or control of the clearing agency or for which it is responsible and, in general, to protect investors and the public interest. Section 17A(b)(3)(F)[8] of the Act also requires that the rules of a clearing agency are not designed to permit unfair discrimination among participants in the use of the clearing agency.

The proposed application of the Firm Trade notional limit to CP affiliate groups is intended to manage what is, in ICC's view, an inappropriate overnight risk to its members without negatively impacting the integrity of its price discovery process. Moreover, the proposed rule change is intended to apply the EOD Policy fairly to participants, and ICC has represented that the proposed rule change is consistent with price submission practices where end-of-day submissions from multiple affiliated entities often reflect the institution's overall view on the market. As such, the Commission believes that the proposed rule change is designed to promote the prompt and accurate clearance and settlement of securities transactions, derivatives agreements, contracts, and transactions within the meaning of Section 17A(b)(3)(F)[9] of the Act.

IV. Conclusion

On the basis of the foregoing, the Commission finds that the proposal is consistent with the requirements of the Act and in particular with the requirements of Section 17A of the Act[10] and the rules and regulations thereunder.[11]

IT IS THEREFORE ORDERED, pursuant to Section 19(b)(2) of the Act,[12] that the proposed rule change (File No. SR–ICC–2016–007) be, and hereby is, approved.[13]

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–19170 Filed 8–11–16; 8:45 am]

BILLING CODE 8011–01–P

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[6] 15 U.S.C. 78s(b)(2)(C).

[7] 15 U.S.C. 78q–1(b)(3)(F).

[8] *Id.*

[9] *Id.*

[10] 15 U.S.C. 78q-1.

[11] 17 CFR 240.17Ad-22.

[12] 15 U.S.C. 78s(b)(2).

[13] In approving the proposed rule change, the Commission considered the proposal's impact on efficiency, competition and capital formation. 15 U.S.C. 78c(f).

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78498; File No. SR–NYSE–2016–52]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 19 To Specify in Exchange Rules the Exchange's Use of Data Feeds From Investors' Exchange, LLC for Order Handling and Execution, Order Routing, and Regulatory Compliance

August 8, 2016.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the "Act")[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on July 26, 2016, New York Stock Exchange LLC ("NYSE" or the "Exchange") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 19 to specify in Exchange rules the Exchange's use of data feeds from Investors' Exchange, LLC for order handling and execution, order routing, and regulatory compliance. The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

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[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 19 to specify in Exchange rules which data feeds from Investors' Exchange, LLC ("IEX") that the Exchange would use for order handling and execution, order routing, and regulatory compliance.

On July 18, 2014, the Exchange filed a proposed rule change that clarified the Exchange's use of certain data feeds for order handling and execution, order routing, and regulatory compliance.[4] As noted in that filing, the data feeds available for the purposes of order handling and execution, order routing, and regulatory compliance at the Exchange include the exclusive securities information processor ("SIP") data feeds.[5] On February 24, 2015, the Exchange adopted Supplementary Material .01 to Rule 19 to specify which data feeds that the Exchange uses for the handling, execution, and routing of orders, as well as for regulatory compliance.[6]

To reflect that IEX's application to register as a national securities exchange has been approved by the Commission[7] and that IEX intends to begin quoting and trading as a registered exchange on August 19, 2016, the Exchange proposes to amend Supplementary Material .01 to Rule 19, to specify which data feeds the Exchange would use for IEX. As proposed, the Exchange would use the SIP Data Feed for IEX and would not have a secondary source.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[8] in general, and furthers the objectives of Section 6(b)(5),[9] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest. The Exchange believes that the proposed rule change removes impediments to and perfects the mechanism of a free and open market because it provides enhanced transparency to better assess the quality of an exchange's execution and routing services.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change is not designed to address any competitive issue but rather would provide the public and investors with information about which data feeds the Exchange uses for execution and routing decisions.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[10] and Rule 19b–4(f)(6) thereunder.[11] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[12]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act[13] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[14] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange states that waiver of the 30-day operative delay would permit the Exchange to immediately enhance transparency and to accommodate the projected date that IEX will begin operating as a national securities exchange. Based on the foregoing, the Commission believes the waiver of the operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the operative delay and designates the proposal operative upon filing.[15]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or

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[4] *See* Securities Exchange Act Release No. 72710 (July 29, 2014), 79 FR 45511 (Aug. 5, 2014) (SR–NYSE–2014–38).

[5] The SIP feeds are disseminated pursuant to effective joint-industry plans as required by Rule 603(b) of Regulation NMS. 17 CFR 242.603(b). The three joint-industry plans are: (1) The CTA Plan, which is operated by the Consolidated Tape Association and disseminates transaction information for securities with the primary listing market on exchanges other than NASDAQ Stock Market LLC ("Nasdaq"); (2) The CQ Plan, which disseminates consolidated quotation information for securities with their primary listing on exchanges other than Nasdaq; and (3) the Nasdaq UTP Plan, which disseminates consolidated transaction and quotation information for securities with their primary listing on Nasdaq.

[6] *See* Securities Exchange Act Release No. 74410 (March 2, 2015), 80 FR 12240 (March 6, 2015) (SR–NYSE–2015–09).

[7] *See* Securities Exchange Act Release No. 78101 (June 17, 2016), 81 FR 41142 (June 23, 2016) (File No. 10–222).

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78s(b)(3)(A)(iii).

[11] 17 CFR 240.19b–4(f)(6).

[12] In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[13] 17 CFR 240.19b–4(f)(6).

[14] 17 CFR 240.19b–4(f)(6)(iii).

[15] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

- Send an email to *rule-comments@sec.gov.* Please include File No. SR–NYSE–2016–52 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–NYSE–2016–52. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–NYSE–2016–52, and should be submitted on or before September 2, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–19176 Filed 8–11–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736.

Extension:

Rule 31 and Form R31, SEC File No. 270–537, OMB Control No. 3235–0597.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for extension of the previously approved collection of information provided for in Rule 31 (17 CFR 240.31) and Form R31 (17 CFR 249.11) under the Securities Exchange Act of 1934 (15 U.S.C. 78ee.) (''Exchange Act'').

Section 31 of the Exchange Act requires the Commission to collect fees and assessments from national securities exchanges and national securities associations (collectively, ''self-regulatory organizations'' or ''SROs'') based on the volume of their securities transactions. To collect the proper amounts, the Commission adopted Rule 31 and Form R31 under the Exchange Act whereby the SROs must report to the Commission the volume of their securities transactions and the Commission, based on those data, calculates the amount of fees and assessments that the SROs owe pursuant to Section 31. Rule 31 and Form R31 require the SROs to provide this data on a monthly basis.

Currently, there are 23 respondents under Rule 31: 19 national securities exchanges, one security futures exchange, and one national securities association subject to the collection of information requirements of Rule 31; there are additionally two registered clearing agencies that are required to provide certain data in their possession needed by the SROs to complete Form R31, although these two entities are not themselves required to complete and submit Form R31. The Commission estimates that the total burden for all 23 respondents is 390 hours per year. The Commission notes that, based on previous and current experience, it estimates an additional three new national securities exchanges will become registered and subject to the reporting requirements of Rule 31 over the course of the authorization period and incur a burden of 18 hours per year. Thus, the Commission estimates the total burden for the existing and expected new respondents to be 408 hours per year.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following Web site: *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: August 9, 2016.

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–19208 Filed 8–11–16; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #14744 and #14745]

Texas Disaster Number TX–00472

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 4.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of Texas (FEMA–4272–DR), dated 06/11/2016.

Incident: Severe Storms and Flooding.

Incident Period: 05/22/2016 through 06/24/2016.

Effective Date: 08/01/2016.

Physical Loan Application Deadline Date: 08/10/2016.

EIDL Loan Application Deadline Date: 03/11/2017.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for the State of Texas, dated 06/11/2016 is hereby amended to re-establish the incident period for this disaster as beginning 05/22/2016 and continuing through 06/24/2016.

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[16] 17 CFR 200.30–3(a)(12).

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2016–19179 Filed 8–11–16; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #14765 and #14766]

Texas Disaster Number TX–00474

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 2.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of Texas (FEMA–4272–DR), dated 07/08/2016.

Incident: Severe Storms and Flooding.

Incident Period: 05/22/2016 through 06/24/2016.

Effective Date: 08/01/2016.

Physical Loan Application Deadline Date: 09/06/2016.

Economic Injury (EIDL) Loan Application Deadline Date: 04/10/2017.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of Texas, dated 07/08/2016, is hereby amended to re-establish the incident period for this disaster as beginning 05/22/2016 and continuing through 06/24/2016.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2016–19169 Filed 8–11–16; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #14765 and #14766]

Texas Disaster Number TX–00474

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 3.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of Texas (FEMA–4272–DR), dated 07/08/2016.

Incident: Severe Storms and Flooding.

Incident Period: 05/22/2016 through 06/24/2016.

Effective Date: 08/01/2016.

Physical Loan Application Deadline Date: 09/06/2016.

Economic Injury (EIDL) Loan Application Deadline Date: 04/10/2017.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of TEXAS, dated 07/08/2016, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties: Hall

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2016–19168 Filed 8–11–16; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #14793 and #14794]

Tennessee Disaster Number TN–00091

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of Tennessee dated 08/02/2016.

Incident: Flash Flooding, Damaging Winds, and Large Hail.

Incident Period: 07/06/2016 through 07/08/2016.

Effective Date: 08/02/2016.

Physical Loan Application Deadline Date: 10/03/2016.

Economic Injury (EIDL) Loan Application Deadline Date: 05/02/2017.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Stewart, Sumner

Contiguous Counties:

Tennessee: Benton, Davidson, Henry, Houston, Macon, Montgomery, Robertson, Trousdale, Wilson.

Kentucky: Allen, Calloway, Christian, Simpson, Trigg.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners With Credit Available Elsewhere	3.250
Homeowners Without Credit Available Elsewhere	1.625
Businesses With Credit Available Elsewhere	6.250
Businesses Without Credit Available Elsewhere	4.000
Non-Profit Organizations With Credit Available Elsewhere	2.625
Non-Profit Organizations Without Credit Available Elsewhere	2.625
For Economic Injury:	
Businesses & Small Agricultural Cooperatives Without Credit Available Elsewhere	4.000
Non-Profit Organizations Without Credit Available Elsewhere	2.625

The number assigned to this disaster for physical damage is 14793 B and for economic injury is 14794 0.

The States which received an EIDL Declaration # are Tennessee, Kentucky.

(Catalog of Federal Domestic Assistance Number 59008)

Dated: August 2, 2016.

Maria Contreras-Sweet,

Administrator.

[FR Doc. 2016–19180 Filed 8–11–16; 8:45 am]

BILLING CODE 8025–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. AB 1100X]

Pacific Harbor Line, Inc.—Discontinuance of Service Exemption—in Los Angeles County, CA

Pacific Harbor Line, Inc. (PHL), a Class III rail carrier, has filed a verified notice of exemption under 49 CFR pt. 1152 subpart F—*Exempt Abandonments and Discontinuances of Service* to discontinue service over an approximately 3.6-mile rail line in the Port of Los Angeles, between approximately milepost 4.00, north of Front Street and east of Gaffey Street Lead, and south to the end of the Line in Los Angeles County, CA (the Line). The Line traverses United States Postal Service Zip Code 90731.

PHL has certified that: (1) No local traffic has moved over the Line for at least two years; (2) overhead traffic on the Line, if any, can be rerouted over other lines; (3) no formal complaint filed by a user of rail service on the Line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the Line either is pending before the Surface Transportation Board or any U.S. District Court or has been decided in favor of a complainant within the two-year period; and (4) the requirements at 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the discontinuance shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) to subsidize continued rail service has been received, this exemption will become effective on September 13, 2016 (50 days after the filing of the exemption), unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues and formal expressions of intent to file an OFA to subsidize continued rail service under 49 CFR 1152.27(c)(2) [1] must be filed by August 22, 2016.[2] Petitions to reopen must be filed by September 1, 2016, with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001.

A copy of any petition filed with the Board should be sent to PHL's representative: Rose-Michele Nardi, 1701 Pennsylvania Ave. NW., Suite 300, Washington, DC 20006.

If the verified notice contains false or misleading information, the exemption is void ab initio.

Board decisions and notices are available on our Web site at "*WWW.STB.DOT.GOV.*"

Decided: August 5, 2016.

By the Board, Joseph H. Dettmar, Acting Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2016–19233 Filed 8–11–16; 8:45 am]

BILLING CODE 4915–01–P

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[1] Each OFA must be accompanied by the filing fee, which is currently set at $1,600. *See* 49 CFR 1002.2(f)(25).

[2] Because PHL is seeking to discontinue service, not to abandon the Line, trail use/rail banking and public use conditions are not appropriate. Because there will be environmental review during abandonment, this discontinuance does not require an environmental review.

SURFACE TRANSPORTATION BOARD

[Docket No. FD 34533 (Sub-No. 1)]

Southwestern Railroad, Inc.—Amended Lease and Operation Exemption—BNSF Railway Company

Southwestern Railroad, Inc. (SWRR), a Class III rail carrier, has filed a verified notice of exemption under 49 CFR 1150.41 to continue to lease and operate approximately 227.6 miles of rail line, located in New Mexico, from BNSF Railway Company (BNSF), as follows: (1) The Carlsbad Subdivision between milepost 0.5 at Clovis and milepost 183.0 at Carlsbad; (2) the Carlsbad Yard; [1] (3) the Carlsbad Industrial Spur between milepost 0.0 at Carlsbad and milepost 20.0 near Carlsbad; and (4) the Loving Industrial Spur between milepost 0.0 at Carlsbad and milepost 20.0 at Loving.

SWRR and BNSF entered into a lease agreement in 2004,[2] and they agreed to a fifth amendment to the lease on June 13, 2016.[3] SWRR states that the current amendment modifies the original agreement to: (1) Change the termination date of the existing agreement to January 17, 2017; and (2) confirm that upon termination, BNSF can immediately renew operations on the line notwithstanding that SWRR will not as of that date have obtained discontinuance authority.

SWRR has certified that its projected annual revenues as a result of this transaction will not exceed those that would qualify it as a Class III rail carrier. SWRR anticipates that its projected annual revenues will exceed $5 million. Therefore, SWRR is required, at least 60 days before this exemption is to become effective, to send notice of the transaction to the national offices of the labor unions with employees on the affected line, to post a copy of the notice at the workplace of the employees on the affected line, and to certify to the Board that it has done so. 49 CFR 1150.42(e). On June 28, 2016, and again in its verified notice of exemption, SWRR certified that on or before June 28, 2016, SWRR complied with the requirements of 49 CFR 1150.42(e) by posting a notice of its intent to undertake the proposed transaction at the workplace of the employees on the affected line. SWRR did not serve a copy of the notice of intent on any labor unions because it asserts the line does not have any unionized labor.

SWRR states that this transaction does not include any interchange commitment that prohibits SWRR from interchanging traffic with a third party or limits SWRR's ability to interchange with a third party.

SWRR states that it expects to consummate the transaction on or after August 28, 2016, the effective date of the exemption (30 days after the verified notice was filed).

If the notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than August 19, 2016 (at least seven days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 34533 (Sub-No. 1), must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, one copy of each pleading must be served on William A. Mullins, Baker & Miller PLLC, 2401 Pennsylvania Ave. NW., Suite 300, Washington, DC 20037.

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[1] SWRR states that there are no mileposts associated with the approximately 5.1 miles of rail line located in the Carlsbad Yard.

[2] *See Sw. R.R.—Lease & Operation Exemption—BNSF Ry.*, FD 34533 (STB served Oct. 22, 2004).

[3] SWRR states that the lease previously had been amended four times and that notice of the most recent amendment requiring Board approval was published in *Southwestern Railroad—Lease & Operation Exemption—BNSF Railway,* FD 35855 (STB served Oct. 1, 2014).

Board decisions and notices are available on our Web site at "*WWW.STB.DOT.GOV.*"

Decided: August 9, 2016.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Tammy Lowery,

Clearance Clerk.

[FR Doc. 2016–19228 Filed 8–11–16; 8:45 am]

BILLING CODE 4915–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. AB 33 (Sub-No. 330X)]

Union Pacific Railroad Company—Discontinuance of Service Exemption—in Port of Los Angeles' San Pedro Subdivision, Los Angeles, CA

Union Pacific Railroad Company (UP) has filed a verified notice of exemption[1] under 49 CFR part 1152 subpart F—*Exempt Abandonments and Discontinuances of Service* to discontinue a 3.6-mile freight rail operating easement over a portion of the San Pedro Industrial Lead a.k.a The West Basin Lead on the San Pedro Subdivision (the Line) in Los Angeles County, CA. The Line extends from milepost 4.00 north of Front Street and east of the Gaffey Street Lead past milepost 6.60, where the track splits, to the end of both the eastern and western leads as shown on Revised Exhibit C to the UP's supplemental notice filed on August 3, 2016. The total mileage for the Line includes both leads. The Line traverses United States Postal Service Zip Code 90731.

UP has certified that: (1) No local or overhead traffic has moved over the Line for at least two years; (2) there is no need to reroute any traffic over other lines; (3) no formal complaint filed by a user of rail service on the Line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the Line is pending either with the Surface Transportation Board (Board) or with any U.S. District Court or has been decided in favor of complainant within the two-year period; and (4) the requirements at 49 CFR 1105.12 (newspaper publication) and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the discontinuance of service shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) to subsidize continued rail service has been received, this exemption will be effective on September 13, 2016, unless stayed pending reconsideration.[2] Petitions to stay that do not involve environmental issues and formal expressions of intent to file an OFA to subsidize continued rail service under 49 CFR 1152.27(c)(2)[3] must be filed by August 22, 2016.[4] Petitions to reopen must be filed by September 1, 2016, with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001.

A copy of any petition filed with the Board should be sent to UP's representative: Mack H. Shumate, Jr., Union Pacific Railroad Company, 101 North Wacker Drive, Room 1920, Chicago, IL 60606.

If the verified notice contains false or misleading information, the exemption is void ab initio.

Board decisions and notices are available on our Web site at "*WWW.STB.DOT.GOV.*"

Decided: August 5, 2016.

By the Board, Joseph H. Dettmar, Acting Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2016–19234 Filed 8–11–16; 8:45 am]

BILLING CODE 4915–01–P

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[1] This notice was originally filed on July 25, 2016. On August 2, 2016, and August 3, 2016, UP filed supplemental information clarifying the milepost designations and the distance on the Line on which it proposes to discontinue its freight easement service.

[2] Although UP states in its verified notice that the proposed consummation date of this transaction is September 10, 2016, this transaction cannot be consummated until September 13, 2016 (50 days from its filing date). 49 CFR 1152.50(d)(2).

[3] Each OFA must be accompanied by the filing fee, which is currently set at $1,600. *See* 49 CFR 1002.2(f)(25).

[4] Because this is a discontinuance proceeding and not an abandonment, interim trail use/rail banking and public use conditions are not appropriate. Because there will be an environmental review during abandonment, this discontinuance does not require an environmental review.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2015–82]

Petition for Exemption; Summary of Petition Received; USA Jet Airlines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Title 14 of the Code of Federal Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before September 1, 2016.

ADDRESSES: Send comments identified by docket number FAA–2015–6560 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200

New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: For technical questions concerning this action, contact Nia Daniels, (202–267–9677), 800 Independence Avenue SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on August 8, 2016.

Dale Bouffiou,

Deputy Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2015–6560.

Petitioner: USA Jet Airlines.

Section of 14 CFR Affected: 121.436(a)(3).

Description of Relief Sought: USA Jet Airlines seeks relief to allow the flight time gained as a Dassault Falcon 20 (DA–20) pilot in command (PIC) operating under § 135.4(a)(1)(2)(i)(ii) and trained and checked under part 121 to count toward the 1,000 hours of flight experience required by § 121.436(a)(3) to serve as PIC in part 121 air carrier operations. This relief would be based upon a proposed alternate means of compliance to allow credit for the certification requirements of Operations Specification A057 and the part 121 training and checking for pilots requiring an airline transport pilot and appropriate type rating flying in USA Jet Airlines' part 135 eligible on-demand cargo operation.

[FR Doc. 2016–19240 Filed 8–11–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2016–88]

Petition for Exemption; Summary of Petition Received; Boeing Executive Flight Operations

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Title 14 of the Code of Federal Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before September 1, 2016.

ADDRESSES: Send comments identified by docket number FAA–2016–8561 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Alphonso W. Pendergrass II (202) 267–4713, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on August 4, 2016.

Dale Bouffiou,

Acting Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2016–8561.

Petitioner: The Boeing Executive Flight Operations.

Section(s) of 14 CFR Affected: 91.527(a).

Description of Relief Sought: Boeing EFO is requesting relief from the requirement that "no person may take off an aircraft when frost, ice, or snow is adhering to any propeller, windshield, or stabilizing control surface; to a powerplant installation; or to an airspeed, altimeter, rate of climb, or flight attitude instrument system or wing, except that takeoffs may be made with frost under the wing in the area of the fuel tanks if authorized by the FAA."

[FR Doc. 2016–19237 Filed 8–11–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2016–84]

Petition for Exemption; Summary of Petition Received; TransPac Aviation Academy

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Title 14 of the Code of Federal Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before September 1, 2016.

ADDRESSES: Send comments identified by docket number {FAA–2016–7131} using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Alphonso W. Pendergrass (202) 267–4713, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on August 5, 2016.

Dale Bouffiou,

Acting Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2016–7131.

Petitioner: TransPac Aviation Academy.

Section(s) of 14 CFR Affected: § 141.63(a)(5)(ii).

Description of Relief Sought: TransPac Aviation Academy request exemption from § 141.63(a)(5)(ii) requirement for a pass rate of 90% in order to be issued an Original Examination Authority for its Part 141 flight school curriculum.

[FR Doc. 2016–19242 Filed 8–11–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2016–94]

Petition for Exemption; Summary of Petition Received; Mr. Karl Beutner

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Title 14 of the Code of Federal Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before September 1, 2016.

ADDRESSES: Send comments identified by docket number FAA–2016–8171 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Alphonso W. Pendergrass II (202) 267–4713, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on August 8, 2016.

Dale Bouffiou,

Acting Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2016–8171.

Petitioner: Mr. Karl Beutner.

Section(s) of 14 CFR Affected: §§ 61.155(c) and (d) and 61.159(a)(2).

Description of Relief Sought: The petitioner requested the FAA extend his eligibility to complete the Airline Transport Pilot (ATP) practical test from July 31, 2016 to July 31, 2017. The petitioner also requested an exemption from § 61.159(a)(2) of title 14, Code of Federal Regulations (14 CFR) to allow the petitioner to take the ATP practical test with less than the required 100 hours of night flight time.

[FR Doc. 2016–19238 Filed 8–11–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice To Rescind Notice of Intent To Prepare Environmental Impact Statement/Draft Section 4(f) Evaluation, MD 28/MD 198 Corridor Study, Montgomery and Prince George's County, Maryland

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice to rescind Notice of Intent to prepare an Environmental Impact Statement/Draft Section 4(f) Evaluation.

SUMMARY: The Federal Highway Administration is issuing this notice to advise the public that FHWA is rescinding its Notice of Intent to prepare an Environmental Impact Statement/Draft Section 4(f) Evaluation for a proposed roadway improvement project in Montgomery and Prince George's Counties, Maryland (**Federal Register** Vol. 68, No. 51827; FR Doc. 03–22037) is being withdrawn and an Environmental Assessment (EA), in lieu of an EIS, is being prepared for this proposed project.

FOR FURTHER INFORMATION CONTACT: Jeanette Mar, Environmental Program Manager, Federal Highway Administration, Maryland Division, 10 South Howard Street, Suite 2450, Baltimore, Maryland 21201, (410) 779–7152, or email: *jeanette.mar@dot.gov.*

SUPPLEMENTARY INFORMATION: The Federal Highway Administration (FHWA), in cooperation with the Maryland State Highway Administration (SHA), is advising the general public that SHA conducted studies of the potential environmental impacts associated with the proposed roadway improvement project in Montgomery and Prince George's Counties, Maryland along the MD 28/MD 198 Corridor between MD 97

(Georgia Avenue) and I–95, a distance of approximately 10.6 miles.

The purpose of the MD 28/MD 198 Corridor Improvement Study is to improve local traffic safety and operations for motorists, bicyclists, and pedestrians traveling along the MD 28/MD 198 corridor and across intersecting roads, while managing access; and, preserve the rural and suburban quality of life by addressing localized traffic issues, while considering local planning visions and state growth policies for communities along the corridor. MD 28 and MD 198 is experiencing peak hour congestion in areas along portions of the corridor between I–95 and MD 97, particularly east of MD 97, in the vicinity of US 29 and Burtonsville commercial area, and near Sweitzer Lane. Local operational and capacity deficiencies are projected to result from planned and future development in and around the study area. The resulting congestion is expected to cause stop-and-go conditions along the roadways, especially at study-area intersections projected to experience failing conditions by 2040. The roadway segments between the intersections will experience peak-hour capacity constraints imposed by: Projected traffic volumes; the absence of mid-block through lanes on two-lane roadways; the absence of storage lanes for left turns; and the absence of deceleration lanes for right turns. Local area master plans describe objectives for the corridor roadway that include retaining the rural character of adjacent communities and protecting sensitive environmental areas. Recommended features in these plans include the construction of hiker-biker trails and sidewalks and the addition of landscaping.

Alternatives under consideration include taking no action, installing on-road bicycle provisions, a shared use path and segments of sidewalk, and widening existing MD 28/MD 198 to a four- or six-lane roadway in some sections, with various options for access management via frontage roads or median treatments, and intersection improvements including additional turn lanes or installing roundabouts. The EA will be available for public and agency review and comment prior to a Public Hearing. Public notice will be given of the availability of the EA for review and of the time and place of this hearing. Public Informational Workshops were held in June 2014 and March 2015 to solicit opinions and ideas on proposed improvements from local citizens.

To ensure that the full range of issues related to this proposed action are addressed and all significant issues identified, comments and suggestions are invited from all interested parties. Comments or questions concerning this proposed action and the determination that an EA is the proper environmental document should be directed to FHWA at the address provided above.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Research, Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Gregory Murrill,

Division Administrator, Federal Highway Administration, Baltimore, Maryland.

[FR Doc. 2016–19197 Filed 8–11–16; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2016–0194]

Agency Information Collection Activities; Renewal of a Currently-Approved Information Collection: Licensing Applications for Motor Carrier Operating Authority

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FMCSA announces its plan to submit the Information Collection Request (ICR) described below to the Office of Management and Budget (OMB) for review and approval and invites public comment. The FMCSA requests approval to renew an ICR titled, "Licensing Applications for Motor Carrier Operating Authority," that is used by for-hire motor carriers of regulated commodities, motor passenger carriers, freight forwarders, property brokers, and certain Mexico-domiciled motor carriers to register their operations with the FMCSA.

DATES: We must receive your comments on or before October 11, 2016.

ADDRESSES: You may submit comments identified by Federal Docket Management System (FDMS) Docket Number FMCSA–2016–0194 using any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building, Ground Floor, Room W12–140, 20590–0001.
- *Hand Delivery or Courier:* West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m. E.T., Monday through Friday, except Federal holidays.

Instructions: All submissions must include the Agency name and docket number. For detailed instructions on submitting comments, see the Public Participation heading below. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov,* and follow the online instructions for accessing the dockets, or go to the street address listed above.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement for the Federal Docket Management System published in the **Federal Register** on January 17, 2008 (73 FR 3316), or you may visit *http://edocket.access.gpo.gov/2008/pdfE8-794.pdf.*

Public Participation: The Federal eRulemaking Portal is available 24 hours each day, 365 days each year. You can obtain electronic submission and retrieval help and guidelines under the "help" section of the Federal eRulemaking Portal Web site. If you want us to notify you that we received your comments, please include a self-addressed, stamped envelope or postcard, or print the acknowledgement page that appears after submitting comments online. Comments received after the comment closing date will be included in the docket and will be considered to the extent practicable.

FOR FURTHER INFORMATION CONTACT: Mr. Jeff Secrist, Office of Registration and Safety Information, Department of Transportation, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. Telephone Number: (202) 385–2367; Email Address: *jeff.secrist@dot.gov.* Office hours are from 8:00 a.m. to 5:00 p.m., E.T., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background: The FMCSA registers certain for-hire Mexico-domiciled motor carriers under 49 U.S.C. 13902(c). These motor carriers may conduct transportation services in the United States only if they are registered with the FMCSA. Each registration is effective from the date specified and remains in effect for such period as the Secretary of Transportation (Secretary) determines by regulations. The ICC Termination Act of 1995 (ICCTA), Public Law 104–88, 109 Stat. 803 (December 29, 1995), transferred this registration authority from the former Interstate Commerce Commission (ICC) to the Secretary who subsequently delegated the registration function to the Federal Highway Administration (FHWA) (FMCSA's predecessor agency), then to the FMCSA at the time that agency was created.

On March 19, 2002, the FMCSA published an interim final rule (IFR) at 67 FR 12702 which proposed to amend 49 CFR part 365 and revise Form OP–1(MX). Under the amended regulations, Mexico-domiciled long-haul motor carriers seeking to operate within the United States beyond the commercial border zones, including carriers that previously filed pending Form OP–1(MX) applications, would be required to submit the revised Form OP–1(MX). Under the revised Form OP–1(MX), the FMCSA would collect more detailed information on an applicant motor carrier's size, operations and history than could be collected previously by using the existing form.

The Final Rule titled, "Unified Registration System," (78 FR 52608) dated August 23, 2013, implemented statutory provisions for an on-line registration system in the ICCTA and the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users, 2005 (SAFETEA–LU). The URS would streamline the registration process and serve as a clearinghouse and repository of information on, and identification of, motor carriers, brokers, freight forwarders, intermodal equipment providers (IEPs), hazardous materials safety permit (HMSP) applicants, and cargo tank facilities required to register with FMCSA. This ICR previously covered registration requirements for non-exempt for-hire carriers, freight forwarders, and property brokers. Under the URS, all forms, except the OP–1(MX), in this ICR were folded into the Form MCSA–1 in the OMB Control Number 2126–0051 titled, "FMCSA Registration/Updates," ICR on October 23, 2015. The Form OP–1(MX) would be retained for the small number of Mexico-domiciled carriers that seek authority to operate beyond the United States municipalities on the United States-Mexico border and their commercial zones because they are not included within the scope of the URS rule.

The Final Rule titled, "Unified Registration System," (80 FR 63695) dated October 21, 2015, changed the effective and compliance dates of the 2013 URS Final Rule from October 23, 2015, to September 30, 2016, in order to allow FMCSA additional time to complete the information technology (IT) systems work required to fully implement that rule. An additional delay was published on July 28, 2016 (81 FR 49553), stating the URS Final Rule will come into effect on January 14, 2017. This ICR revision will restore the Forms OP–1, OP–1(P), OP–1(FF), and OP–1(NNA) under control number 2126–0016, until January 14, 2017, because these forms are still needed to support registration processes for entities subject to FMCSA's regulations. After January 14, 2017, all forms in this ICR, except the OP–1 (MX), will be folded into the online Form MCSA–1 under the OMB Control Number 2126–0051 titled, "FMCSA Registration/Updates," ICR.

Title: Licensing Applications for Motor Carrier Operating Authority.

OMB Control Number: 2126–0016.

Type of Request: Renewal of a currently approved collection.

Respondents: Motor carriers, motor passenger carriers, freight forwarders, brokers, and certain Mexico-domiciled motor carriers.

Estimated Number of Respondents and Responses: 36 respondents [(12 respondents and responses for Year 1) + (12 respondents and responses for Year 2) + (12 respondents and responses for Year 3)].

Estimated Time per Response: 4 hours.

Expiration Date: October 31, 2016

Frequency of Response: Other (as needed).

Estimated Total Annual Burden: 48 hours [48 hours for Year 1 + 48 hours for Year 2 + 48 hours for Year 3 = 133 hours/3 year approval for ICR = 48 estimated average number of annual burden hours].

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the performance of FMCSA's functions; (2) the accuracy of the estimated burden; (3) ways for FMCSA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize or include your comments in the request for OMB's clearance of this information collection.

Issued on: August 1, 2016.

G. Kelly Regal,

Associate Administrator for Office of Research and Information Technology.

[FR Doc. 2016–18988 Filed 8–11–16; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. DOT–MARAD 2016–0076]

Agency Requests for Renewal of a Previously Approved Information Collection(s): Merchant Marine Medals and Awards

AGENCY: Maritime Administration, DOT.

ACTION: Notice and request for comments.

SUMMARY: The Maritime Administration (MARAD) invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The information collected will be used by MARAD personnel to process and verify requests for service awards. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995, Public Law 104–13.

DATES: Written comments should be submitted by October 11, 2016.

ADDRESSES: You may submit comments [identified by Docket No. DOT–MARAD–2016–0076] through one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 1–202–493–2251.
- *Mail or Hand Delivery:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

FOR FURTHER INFORMATION CONTACT: Deveeda Midgette, 202–366–2354, Maritime Administration, Office of Sealift Support, 1200 New Jersey Avenue SE., Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2133–0506.

Title: Merchant Marine Medals and Awards.

Form Numbers: None.

Type of Review: Renewal of an information collection.

Background: This information collection of information provides a method of awarding merchant marine medals and decorations to masters, officers, and crew members of U.S. ships in recognition of their service in areas of danger during the operations by the Armed Forces of the United States in World War II, Korea, Vietnam, and Operation Desert Storm.

Respondents: Master, officers and crew members of U.S. ships.

Number of Respondents: 550.

Number of Responses: 550.

Total Annual Burden: 550.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) whether the proposed collection of information is necessary for the Department's performance; (b) the accuracy of the estimated burden; (c) ways for the Department to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1:93.

By Order of the Maritime Administrator.

Dated: July 28, 2016.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2016–19262 Filed 8–11–16; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2016 0081]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel TENACITY; Invitation for Public Comments

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice.

SUMMARY: As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before September 12, 2016.

ADDRESSES: Comments should refer to docket number MARAD–2016–0081. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel TENACITY is:

Intended Commercial Use of Vessel: Private Vessel Charters.

Geographic Region: "Maine, New Hampshire, Massachusetts, Rhode Island, Connecticut, New York, New Jersey, Pennsylvania, Delaware, Maryland, Virginia, North Carolina, South Carolina, Georgia, Florida, California, Oregon, Washington, and Alaska (excluding waters in Southeastern Alaska and waters north of a line between Gore Point to Cape Suckling [including the North Gulf Coast and Prince William Sound])"

The complete application is given in DOT docket MARAD–2016–0081 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

By Order of the Maritime Administrator.

Dated: August 4, 2016.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2016–19249 Filed 8–11–16; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2016 0080]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel SURGE; Invitation for Public Comments

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice.

SUMMARY: As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before September 12, 2016.

ADDRESSES: Comments should refer to docket number MARAD–2016–0080. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., ET, Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel SURGE is:

Intended Commercial Use of Vessel: "Day sail charters out of Florida in the winter and New England in the summer."

Geographic Region: "Florida, Rhode Island, Maine, Massachusetts"

The complete application is given in DOT docket MARAD–2016–0080 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

By Order of the Maritime Administrator.

Dated: August 4, 2016.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2016–19266 Filed 8–11–16; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2016 0079]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel MATTARAY; Invitation for Public Comments

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice.

SUMMARY: As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before September 12, 2016.

ADDRESSES: Comments should refer to docket number MARAD–2016–0079. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., ET, Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel MATTARAY is:

Intended Commercial Use of Vessel: "Small (six pack-up to six people) fishing charters"

Geographic Region: "California"

The complete application is given in DOT docket MARAD–2016–0079 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

By Order of the Maritime Administrator.

Dated: August 4, 2016.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2016–19263 Filed 8–11–16; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2016 0078]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel PWD #315; Invitation for Public Comments

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice.

SUMMARY: As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before September 12, 2016.

ADDRESSES: Comments should refer to docket number MARAD–2016–0078. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., ET, Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel PWD #315 is:

Intended Commercial Use of Vessel: "Cafe Bed and Breakfast"

Geographic Region: "Washington State"

The complete application is given in DOT docket MARAD–2016–0078 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

By Order of the Maritime Administrator.

Dated: August 4, 2016.

T. Mitchell Hudson, Jr.

Secretary, Maritime Administration.

[FR Doc. 2016–19257 Filed 8–11–16; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2016–0083]

National Emergency Medical Services Advisory Council (NEMSAC); Notice of Federal Advisory Committee Meeting

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: The NHTSA announces meeting of NEMSAC to be held in the Metropolitan Washington, DC, area. This notice announces the date, time, and location of the meetings, which will be open to the public, as well as opportunities for public input to the NEMSAC. The purpose of NEMSAC, a nationally recognized council of emergency medical services representatives and consumers, is to advise and consult with DOT and the Federal Interagency Committee on Emergency Medical Services (FICEMS) on matters relating to emergency medical services (EMS).

DATES: The NEMSAC meeting will be held on September 7, 2016 from 8:30 a.m. to 12:30 p.m. EDT, and on September 8, 2016 from 8:30 a.m. to 12 p.m. EDT. A public comment period will take place on September 7, 2016 between 12 p.m. and 12:30 p.m. EDT and on September 8, 2016 between 10:45 a.m. and 11 a.m. EDT. NEMSAC committees will meet in the same location on Wednesday, September 7, 2016 from 2 p.m. to 5 p.m. EDT. Written comments for the NEMSAC from the public must be received no later than September 1, 2016.

ADDRESSES: The meetings will be held at the FHI 360 Conference Center, 8th Floor, 1825 Connecticut Avenue NW., Washington, DC 20009. Attendees should plan to arrive 20 minutes early to check in for the meeting.

FOR FURTHER INFORMATION CONTACT: Susan McHenry, U.S. Department of Transportation, Office of Emergency Medical Services, 1200 New Jersey Avenue SE., NTI–140, Washington, DC 20590, *susan.mchenry@dot.gov* or 202–366–6540.

SUPPLEMENTARY INFORMATION: Notice of these meetings is given under the Federal Advisory Committee Act, Public Law 92–463, as amended (5 U.S.C. App.). The NEMSAC is authorized under Section 31108 of the Moving Ahead with Progress in the 21st Century Act of 2012.

Tentative Agenda of the National EMS Advisory Council Meeting

The tentative NEMSAC agenda includes the following:

Wednesday, September 7, 2016, (8:30 a.m. to 12:30 p.m. EDT)

(1) Opening Remarks
(2) Disclosure of Conflicts of Interests by Members
(3) Federal Liaison Update—Reports and Updates from the Departments of Transportation, Homeland Security, and Health & Human Services
(4) NEMSAC Committee Updates
(5) Public Comment (12 p.m.–12:30 p.m. EDT)
(6) Recess for Day (12:30 p.m. EDT)
NEMSAC Committees Breakout Sessions from 2 p.m.–5 p.m.—(on-site and open to the public)

Thursday, September 8, 2016 (8:30 a.m. to 12 p.m. EDT)

(1) Reconvene and Approval of April 18–19, 2016 Meeting Minutes
(2) NEMSAC Committee Reports (see committee list below)
(3) Public Comment (10:45 a.m.–11 a.m. EDT)
(4) Election of Chair and Vice Chair
(5) Next Steps
(6) Adjourn—12 p.m. EDT

Overview of NEMSAC Committees:

a. Funding and Reimbursement
b. Innovative Practices of EMS Workforce
c. Data Integration and Technology
d. Patient Care, Quality Improvement and General Safety
e. Provider and Community Education
f. Ad Hoc Committee on Recognition of EMS Personnel Licensure Interstate Compact (REPLICA)
g. Ad Hoc Committee on EMS Scope of Practice Model & Administration of Narcotic Antagonists

Registration Information: This meeting will be open to the public; however, pre-registration is requested. Individuals wishing to attend must register online no later than September 1, 2016. For NEMSAC please register at: *http://www.cvent.com/d/9vq7db/4W.*

For assistance with registration, please contact Susan McHenry at *Susan.Mchenry@dot.gov* or at 202–366–6540. There will not be a teleconference option for these meetings.

Public Comment: Members of the public are encouraged to comment directly to the NEMSAC during designated public comment periods. In order to allow as many people as possible to speak, speakers are requested to limit their remarks to 5 minutes. Written comments from members of the public will be distributed to NEMSAC members at the meeting and should reach the NHTSA Office of EMS no later than September 1, 2016. Written comments may be submitted by either one of the following methods: (1) You may submit comments by email: *nemsac@dot.gov* or (2) you may submit comments by fax: 202–366–7149.

A final agenda as well as meeting materials will be available to the public online through *www.EMS.gov* on or before August 29, 2016.

Issued on: August 9, 2016.

Jeffrey P. Michael,

Associate Administrator for Research and Program Development.

[FR Doc. 2016–19215 Filed 8–11–16; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8911

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently, the IRS is soliciting comments concerning Form 8911, Alternative Fuel Vehicle Refueling Property Credit.

DATES: Written comments should be received on or before October 11, 2016 to be assured of consideration.

ADDRESSES: Direct all written comments to Tuawana Pinkston, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Sara Covington, at Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the internet at *Sara.L.Covington@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Alternative Fuel Vehicle Refueling Property Credit.

OMB Number: 1545–1981.

Form Number: Form 8911.

Abstract: IRC section 30C allows a credit for alternative fuel vehicle refueling property. Form 8911, Alternative Fuel Vehicle Refueling Property Credit, will be used by taxpayers to claim the credit.

Current Actions: There is no change in the paperwork burden previously approved by OMB. This form is being submitted for renewal purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profit organizations.

Estimated Number of Respondents: 300,330.

Estimated Time per Respondent: 11 hours .39

Estimated Total Annual Burden Hours: 3,420,759.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: July 21, 2016.

Tuawana Pinkston,

IRS Supervisory Tax Analyst.

[FR Doc. 2016–18635 Filed 8–11–16; 8:45 am]

BILLING CODE 4830–01–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION
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Part II

Securities and Exchange Commission

17 CFR Part 242
Regulation SBSR—Reporting and Dissemination of Security-Based Swap Information; Final Rule

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 242

[Release No. 34–78321; File No. S7–03–15]

RIN 3235–AL71

Regulation SBSR—Reporting and Dissemination of Security-Based Swap Information

AGENCY: Securities and Exchange Commission.

ACTION: Final rule.

SUMMARY: The Securities and Exchange Commission ("SEC" or "Commission") is adopting certain amendments to Regulation SBSR—Reporting and Dissemination of Security-Based Swap Information ("Regulation SBSR"). Specifically, new Rule 901(a)(1) of Regulation SBSR requires a platform (*i.e.,* a national securities exchange or security-based swap execution facility ("SB SEF") that is registered with the Commission or exempt from registration) to report a security-based swap executed on such platform that will be submitted to clearing. New Rule 901(a)(2)(i) of Regulation SBSR requires a registered clearing agency to report any security-based swap to which it is a counterparty. The Commission is adopting certain conforming amendments to other provisions of Regulation SBSR in light of the newly adopted amendments to Rule 901(a), and an amendment that would require registered security-based swap data repositories ("SDRs") to provide the security-based swap transaction data that they are required to publicly disseminate to the users of the information on a non-fee basis. The Commission also is adopting amendments to Rule 908(a) to extend Regulation SBSR's regulatory reporting and public dissemination requirements to additional types of cross-border security-based swaps. The Commission is offering guidance regarding the application of Regulation SBSR to prime brokerage transactions and to the allocation of cleared security-based swaps. Finally, the Commission is adopting a new compliance schedule for the portions of Regulation SBSR for which the Commission has not previously specified compliance dates.

DATES: *Effective Date:* October 11, 2016.

Compliance Dates: For a discussion of the Compliance Dates for Regulation SBSR, *see* Section X of the Supplementary Information.

FOR FURTHER INFORMATION CONTACT: Michael Gaw, Assistant Director, at (202) 551–5602; Sarah Albertson, Special Counsel, at (202) 551–5647; Yvonne Fraticelli, Special Counsel, at (202) 551–5654; Kathleen Gross, Special Counsel, at (202) 551–5305; David Michehl, Special Counsel, at (202) 551–5627; or Geoffrey Pemble, Special Counsel, at (202) 551–5628; all of the Division of Trading and Markets, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–7010.

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Section 13A(a)(1) of the Exchange Act[1] provides that each security-based swap that is not accepted for clearing by any clearing agency or derivatives clearing organization shall be subject to regulatory reporting. Section 13(m)(1)(G) of the Exchange Act[2] provides that each security-based swap (whether cleared or uncleared) shall be reported to a registered SDR, and Section 13(m)(1)(C) of the Exchange Act[3] generally provides that transaction, volume, and pricing data of security-based swaps shall be publically disseminated in real time.[4]

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[1] 15 U.S.C. 78m–1(a)(1). All references in this release to the Exchange Act refer to the Securities Exchange Act of 1934.

[2] 15 U.S.C. 78m(m)(1)(G).

[3] 15 U.S.C. 78m(m)(1)(C).

In February 2015, the Commission adopted Regulation SBSR,[5] which consists of Rules 900 to 909 under the Exchange Act and provides for the regulatory reporting and public dissemination of security-based swap transactions. At the same time that it adopted Regulation SBSR, the Commission also proposed certain additional rules and guidance relating to regulatory reporting and public dissemination of security-based swap transactions that were not addressed in the Regulation SBSR Adopting Release.[6] In April 2015, the Commission proposed certain rules that would address the application of Title VII requirements to security-based swap activity engaged in by non-U.S. persons within the United States,[7] including how Regulation SBSR would apply to such activity, and certain related issues. In this release, the Commission is adopting, with a number of revisions, the amendments to Regulation SBSR contained in the Regulation SBSR Proposed Amendments Release and the U.S. Activity Proposal.

The Commission received 18 comments on the Regulation SBSR Proposed Amendments Release[8] and 16 comments on the U.S. Activity Proposal, of which seven addressed issues relating to Regulation SBSR.[9] Below, the Commission responds to issues raised in those comments and discusses the amendments to Regulation SBSR being adopted herein. Some commenters directed comments to the rules the Commission already adopted in the Regulation SBSR Adopting Release.[10] As the Commission stated in the Regulation SBSR Proposed Amendments Release, however, the Commission did not reopen comment on the rules that it adopted in the Regulation SBSR Adopting Release.[11] Accordingly, these comments are beyond the scope of this release and are not addressed herein.

II. Economic Considerations and Baseline Analysis

To provide context for understanding the rules being adopted today and the related economic analysis that follows, this section describes the current state of the security-based swap market and the existing regulatory framework; it also identifies broad economic considerations that underlie the likely economic effects of these rules.

A. Baseline

To assess the economic impact of the final rules described in this release, the Commission employs as a baseline the security-based swap market as it exists at the time of this release, including applicable rules that the Commission already has adopted but excluding rules that the Commission has proposed but not yet finalized.[12] The analysis includes the statutory and regulatory provisions that currently govern the security-based swap market pursuant to the Dodd-Frank Act, rules adopted in the Intermediary Definitions Adopting Release,[13] the Cross-Border Adopting Release,[14] the SDR Adopting Release,[15] and the U.S. Activity Adopting Release.[16] In addition, the baseline includes rules that have been adopted but for which compliance is not yet required, including the SBS Entity Registration Adopting Release,[17] the Regulation SBSR Adopting Release,[18] and the External Business Conduct Adopting Release,[19] as these final rules—even if compliance is not required—are part of the existing regulatory landscape that market participants must take into account when conducting their security-based swap activity.

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[4] In addition, Section 13(m)(1)(E) of the Exchange Act, 15 U.S.C. 78m(m)(1)(E), provides that, with respect to cleared security-based swaps, the rule promulgated by the Commission related to public dissemination shall contain provisions, among others, that "specify the criteria for determining what constitutes a large notional security-based swap transaction (block trade) for particular markets and contracts" and "specify the appropriate time delay for reporting large notional security-based swap transactions (block trades) to the public."

[5] Securities Exchange Act Release No. 74244 (February 11, 2015), 80 FR 14564 (March 19, 2015) ("Regulation SBSR Adopting Release"). The Commission initially proposed Regulation SBSR in November 2010. *See* Securities Exchange Act Release No. 63346 (November 19, 2010), 75 FR 75207 (December 2, 2010) ("Regulation SBSR Proposing Release"). In May 2013, the Commission re-proposed the entirety of Regulation SBSR as part of a larger release that proposed rules and interpretations regarding the application of Title VII of the Dodd-Frank Act ("Title VII") to cross-border security-based swap activities. *See* Securities Exchange Act Release No. 69490 (May 1, 2013), 78 FR 30967 (May 23, 2013) ("Cross-Border Proposing Release").

[6] Securities Exchange Act Release No. 74244 (February 11, 2015), 80 FR 14740 (March 19, 2015) ("Regulation SBSR Proposed Amendments Release").

[7] Securities Exchange Act Release No. 74834 (April 29, 2015), 80 FR 27444 (May 13, 2015) ("U.S. Activity Proposal").

[8] *See* letters to Brent J. Fields, Secretary, Commission, from Larry E. Thompson, Vice Chairman and General Counsel, Depository Trust & Clearing Corporation ("DTCC"), dated May 4, 2015 ("DTCC Letter"); Susan Milligan, Head of U.S. Public Affairs, LCH.Clearnet Group Limited, dated May 4, 2015 ("LCH.Clearnet Letter"); Marcus Schüler, Head of Regulatory Affairs, Markit, dated May 4, 2015 ("Markit Letter"); and Vincent A. McGonagle, Director, Division of Market Oversight, and Phyllis P. Dietz, Acting Director, Division of Clearing and Risk, Wholesale Market Brokers' Association, Americas ("WMBAA"), dated May 4, 2015 ("WMBAA Letter"); letters to Elizabeth M. Murphy, Secretary, Commission, from Marisol Collazo, Chief Executive Officer, DTCC Data Repository (U.S.) LLC, Bruce A. Tupper, President, ICE Trade Vault, LLC, and Jonathan A. Thursby, Global Head of Repository Services, CME Group, dated June 10, 2015 ("DTCC/ICE/CME Letter"); Kara Dutta, General Counsel, and Bruce A. Tupper, President, ICE Trade Vault, LLC, dated May 4, 2015 ("ICE Letter"); Tara Kruse, Director, Co-Head of Data, Reporting, and FpML, International Swaps and Derivatives Association, Inc. ("ISDA"), and Kyle Brandon, Managing Director, Director of Research, Securities Industry and Financial Markets Association ("SIFMA"), dated May 4, 2015 ("ISDA/SIFMA Letter"); undated letter from Timothy W. Cameron, Managing Director-Head, and Laura Martin, Managing Director and Associate General Counsel, Asset Management Group, SIFMA ("SIFMA–AMG II"); letters to the Secretary, Commission, from Dennis M. Kelleher, President and Chief Executive Officer, Stephen W. Hall, Securities Specialist, and Todd Philips, Attorney, Better Markets, Inc., dated May 4, 2015 ("Better Markets Letter"); Allan D. Grody, President, Financial InterGroup Holdings Ltd, dated May 18, 2015 ("Financial InterGroup Letter"); and Tara Kruse, Director, Co-Head of Data, Reporting, and FpML, ISDA, dated November 25, 2015 ("ISDA III"); letter to Michael Gaw, Assistant Director, Office of Market Supervision ("OMS"), Division of Trading and Markets, Commission, from Bert Fuqua, General Counsel, Investment Bank Americas Legal, UBS AG, and Michael Loftus, Managing Director, Investment Bank Americas Legal, UBS AG, dated May 6, 2016 ("UBS Letter"); letter to Michael Gaw, Assistant Director, OMS, Division of Trading and Markets ("Division"), Commission, and Tom Eady, Senior Policy Advisor, Division, Commission, from Tara Kruse, Director, Co-Head of Data, Reporting and FpML, ISDA, dated August 3, 2015 ("ISDA II"); letter from Chris Barnard, dated May 4, 2015 ("Barnard I"). Four comments, although submitted to the comment file for the Regulation SBSR Proposed Amendments Release, were not germane to the proposal and are not considered here.

[9] *See* UBS Letter and letters to Brent J. Fields, Secretary, Commission, from Dan Waters, Managing Director, ICI Global, dated July 13, 2015 ("ICI Global Letter"); Sarah A. Miller, Chief Executive Officer, Institute of International Bankers ("IIB"), dated July 13, 2015 ("IIB Letter"); David Geen, General Counsel, ISDA, dated July 13, 2015 ("ISDA I"); Timothy W. Cameron, Managing Director-Head, and Laura Martin, Managing Director and Associate General Counsel, Asset Management Group, SIFMA, dated July 13, 2015 ("SIFMA–AMG I"); Kenneth E. Bentsen, Jr., President and Chief Executive Officer, SIFMA, and Rich Foster, Senior Vice President and Senior Counsel for Regulatory and Legal Affairs, Financial Services Roundtable ("FSR"), dated July 13, 2015 ("SIFMA/FSR Letter"); letter from Chris Barnard, dated June 26, 2015 ("Barnard II").

[10] The issues raised by these commenters included, for example, the 24-hour reporting delay adopted in the Regulation SBSR Adopting Release; the ability to report all transaction information required by Regulation SBSR in light of certain foreign privacy laws; the identification of indirect counterparties; public dissemination of certain illiquid security-based swaps; the requirement for registered SDRs to disseminate the full notional size of all transactions; and the requirement that a registered SDR immediately disseminate information upon receiving a transaction report.

[11] *See* 80 FR at 14741, n. 8.

[12] The Commission also considered, where appropriate, the impact of rules and technical standards promulgated by other regulators, such as the CFTC and the European Securities and Markets Authority ("ESMA"), on practices in the security-based swap market.

[13] *See* Securities Exchange Act Release No. 66868 (April 27, 2012), 77 FR 30596 (May 23, 2012) ("Intermediary Definitions Adopting Release").

[14] *See* Securities Exchange Act Release No. 72472 (June 25, 2014), 79 FR 47278 (August 12, 2014) ("Cross-Border Adopting Release").

[15] *See* Securities Exchange Act Release No. 74246 (February 11, 2015), 80 FR 14438 (March 19, 2015) ("SDR Adopting Release").

[16] *See* Securities Exchange Act Release No. 77104 (February 10, 2016), 81 FR 8598 (February 19, 2016) ("U.S. Activity Adopting Release").

The following sections provide an overview of aspects of the security-based swap market that are likely to be most affected by the amendments and guidance being adopted today, as well as elements of the current market structure, such as central clearing and platform trading, that are likely to determine the scope of transactions that will be covered by them.

1. Available Data Regarding Security-Based Swap Activity

The Commission's understanding of the market is informed in part by available data on security-based swap transactions, though the Commission acknowledges that limitations in the data prevent the Commission from quantitatively characterizing certain aspects of the market.[20] Because these data do not cover the entire market, the Commission has developed an understanding of market activity using a sample of transaction data that includes only certain portions of the market. The Commission believes, however, that the data underlying its analysis here provide reasonably comprehensive information regarding single-name credit default swap ("CDS") transactions and the composition of participants in the single-name CDS market.

Specifically, the Commission's analysis of the state of the current security-based swap market is based on data obtained from the DTCC Derivatives Repository Limited Trade Information Warehouse ("TIW"), especially data regarding the activity of market participants in the single-name CDS market during the period from 2008 to 2015. According to data published by the Bank for International Settlements ("BIS"), the global notional amount outstanding in single-name CDS was approximately $7.18 trillion,[21] in multi-name index CDS was approximately $4.74 trillion, and in multi-name, non-index CDS was approximately $373 billion. The total gross market value outstanding in single-name CDS was approximately $284 billion, and in multi-name CDS instruments was approximately $137 billion.[22] The global notional amount outstanding in equity forwards and swaps as of December 2015 was $3.32 trillion, with total gross market value of $147 billion.[23] As these figure show (and as the Commission has previously noted), although the definition of security-based swaps is not limited to single-name CDS, single-name CDS make up a vast majority of security-based swaps in terms of notional amount outstanding, and the Commission believes that the single-name CDS data are sufficiently representative of the market to inform the Commission's analysis of the state of the current security-based swap market.[24]

The Commission notes that the data available to it from TIW do not encompass those CDS transactions that both: (1) Do not involve U.S. counterparties; [25] and (2) are based on non-U.S. reference entities. Notwithstanding this limitation, the TIW data should provide sufficient information to permit the Commission to identify the types of market participants active in the security-based swap market and the general pattern of dealing within that market.[26]

One commenter recommended that the Commission collect a more complete set of data to more precisely estimate the number of non-U.S. persons that would be affected by the proposed rules.[27] Given the absence of comprehensive reporting requirements for security-based swap transactions, and the fact that the location of personnel that arrange, negotiate, or execute a security-based swap transaction is not currently available in TIW, a more precise estimate of the number of non-U.S. persons affected by the adopted rules is not currently feasible.

2. Clearing Activity in Single-Name CDS

Currently, there is no regulatory requirement in the United States to clear security-based swaps. Clearing for certain single-name CDS products occurs on a voluntary basis. Voluntary clearing activity in single-name CDS has steadily increased in recent years. As of the end of 2015, ICE Clear Credit accepted for clearing security-based swap products based on a total of 232 North American corporate reference entities, 174 European corporate reference entities, and 21 individual sovereign reference entities.

Figure 1, below, shows characteristics of new trades in single-name CDS that reference North American standard corporate ISDA documentation. In particular, the figure documents that about half of all clearable transactions are cleared. Analysis of trade activity from January 2011 to December 2015 indicates that, out of $3,460 billion of notional amount traded in North American corporate single-name CDS products that are accepted for clearing during the 60 months ending December 2015, approximately 70%, or $2,422 billion, had characteristics making them suitable for clearing by ICE Clear Credit and represented trades between two ICE Clear Credit clearing members. Approximately 80% of this notional value, or $1,938 billion, was cleared through ICE Clear Credit, or 56% of the total volume of new trade activity. As of the end of 2015, ICE Clear Europe accepted for clearing single-name CDS products referencing a total of 176 European corporate reference entities and seven sovereign reference entities. Analysis of new trade activity from January 2011 to December 2015 indicates that, out of €1,963 billion of notional volume traded in European corporate single-name CDS products that are accepted for clearing during the 60 months ending December 2015, approximately 58%, or €1,139 billion, had characteristics making them suitable for clearing by ICE Clear Europe and represented trades between two ICE Clear Europe clearing members. Approximately 71% of this notional amount, or €805 billion, was cleared through ICE Clear Europe, or 41% of the total volume of new trade activity.[28]

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[17] *See* Securities Exchange Act Release No. 75611 (August 5, 2015), 80 FR 48963 (August 14, 2015) ("SBS Entities Registration Adopting Release").

[18] *See supra* note 5.

[19] *See* Securities Exchange Act Release No. 77617 (April 14, 2016), 81 FR 29960 (May 13, 2016) ("External Business Conduct Adopting Release").

[20] The Commission also relies on qualitative information regarding market structure and evolving market practices provided by commenters, both in letters and in meetings with Commission staff, and knowledge and expertise of Commission staff.

[21] The global notional amount outstanding represents the total face amount of the swap used to calculate payments. The gross market value is the cost of replacing all open contracts at current market prices.

[22] *See* Semi-annual OTC derivatives statistics (December 2015), Table D5, available at *http://www.bis.org/statistics/derstats.htm* (last viewed May 25, 2016).

[23] These totals include both swaps and security-based swaps, as well as products that are excluded from the definition of "swap," such as certain equity forwards.

[24] *See* U.S. Activity Adopting Release, 81 FR at 8601.

[25] The Commission has classified accounts as "U.S. counterparties" based on TIW's entity domicile determinations. The Commission notes, however, that TIW's entity domicile determinations are not necessarily identical in all cases to the definition of "U.S. person" under Exchange Act Rule 3a71–3(a)(4), 17 CFR 240.3a71–3(a)(4).

[26] The challenges the Commission faces in estimating measures of current market activity stems, in part, from the absence of comprehensive reporting requirements for security-based swap market participants. The Commission has adopted rules regarding trade reporting, data elements, and public reporting for security-based swaps that are designed to, when fully implemented, provide us with appropriate measures of market activity. *See* Regulation SBSR Adopting Release, 80 FR at 14699–700.

[27] *See* ISDA Letter at 3, 7 (arguing that the Commission lacks complete data to estimate the number of non-U.S. persons that use U.S. personnel to arrange, negotiate, or execute security-based swap transactions or the number of registered U.S. broker-dealers that intermediate these transactions and that this "makes it difficult or impossible for the Commission to formulate a useful estimate of the market impact, cost and benefits of the Proposal"; suggesting that the Commission "gather[ ] more robust and complete data prior to finalizing a rulemaking that will have meaningful impact on a global market").

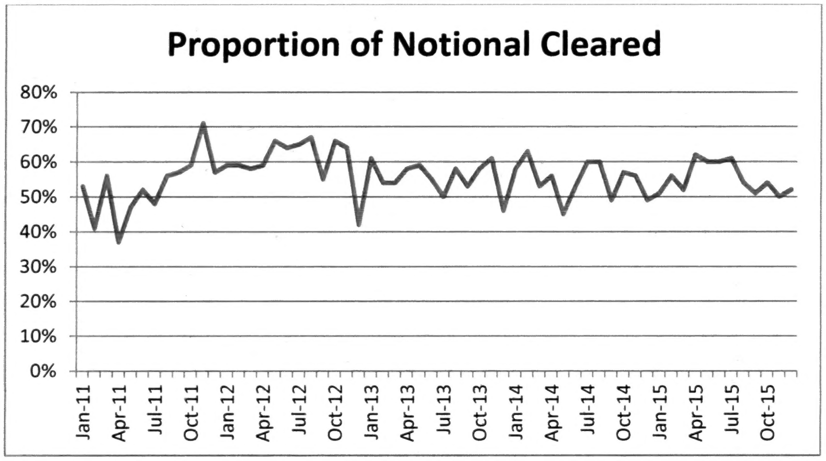

Figure 1: The fraction of total gross notional amount of new trades and assign-entries in North American single-name CDS products that were accepted for clearing by ICE Clear Credit and were cleared within 14 days of the initial transaction.[29]

3. Current Market Structure for Security-Based Swap Infrastructure

a. Exchanges and SB SEFs

The rules and amendments adopted herein address how transactions conducted on platforms (*i.e.*, national securities exchanges and SB SEFs) must be reported under Regulation SBSR. Currently, there are no SB SEFs registered with the Commission, and as a result, there is no registered SB SEF trading activity to report. There are, however, currently 22 swap execution facilities (''SEFs'') that are either temporarily registered with the Commodity Futures Trading Commission (''CFTC'') or whose temporary registrations are pending with the CFTC and currently are exempt from registration with the Commission.[30] As the Commission noted in the U.S. Activity Adopting Release, the cash flows of security-based swaps and other swaps are closely related and many participants in the swap market also participate in the security-based swap market.[31] Likewise, the Commission believes that it is possible that some entities that currently act as SEFs will register with the Commission as SB SEFs. The Commission anticipates that, owing to the smaller size of the security-based swap market, there will be fewer platforms for executing transactions in security-based swaps than the 22 SEFs reported within the CFTC's jurisdiction. Under newly adopted Rule 901(a)(1), a platform is required to report to a registered SDR any security-based swap transaction that is executed on the platform and submitted to clearing.

b. Clearing Agencies

The market for clearing services in the security-based swap market is currently concentrated among a handful of firms. Table 1 lists the firms that currently clear index and single-name CDS and identifies the segments of the market each firm serves. While there may be several choices available to participants interested in cleared index CDS transactions, only two firms (albeit with the same parent) clear sovereign single-name CDS and only a single firm serves the market for North American single-name CDS. Concentration of clearing services within a limited set of clearing agencies can be explained, in part, by the existence of strong economies of scale in central clearing.[32]

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[28] These numbers do not include transactions in European corporate single-name CDS that were cleared by ICE Clear Credit. During the sample period, a total of 2,168 transactions in European corporate single-name CDS (with a total gross notional amount of approximately €11 billion) were cleared by ICE Clear Credit. All but one of these transactions occurred between 2014 and 2015. For historical data, *see https://www.theice.com/marketdata/reports/99* (last visited on May 25, 2016).

[29] The Commission believes that it is reasonable to assume that, when clearing occurs within 14 days of execution, counterparties made the decision to clear at the time of execution and not as a result of information arriving after execution.

[30] *See* Securities Exchange Act Release No. 64678 (June 15, 2011), 76 FR 36287, at 36306 (June 22, 2011) (Temporary Exemptions and Other Temporary Relief, Together With Information on Compliance Dates for New Provisions of the Securities Exchange Act of 1934 Applicable to Security-Based Swaps) (''Effective Date Release'') (exempting persons that operate a facility for the trading or processing of security-based swaps that is not currently registered as a national securities exchange or that cannot yet register as an SB SEF because final rules for such registration have not yet been adopted from the requirements of Section 3D(a)(1) of the Exchange Act until the earliest compliance date set forth in any of the final rules regarding registration of SB SEFs). A list of SEFs that are either temporarily registered with the CFTC or whose temporary registrations are pending with the CFTC is available at *http://sirt.cftc.gov/SIRT/SIRT.aspx?Topic=SwapExecutionFacilities* (last visited May 25, 2016).

[31] *See* 81 FR at 8609.

The rules adopted today will, among other things, assign regulatory reporting duties for clearing transactions (*i.e.,* security-based swaps to which registered clearing agencies are direct counterparties). Any rule that would assign reporting duties for clearing transactions would affect the accessibility of data related to a large number of security-based swap transactions. In addition, the number of clearing transactions would affect the magnitude of the regulatory burdens associated with those reporting duties.

TABLE 1—CLEARING AGENCIES CURRENTLY CLEARING INDEX AND SINGLE-NAME CDS

	North American	European	Japanese	Sovereign	Index
ICE Clear Credit [33]	X	X		X	X
ICE Clear Europe [34]		X		X	X
CME [35]					X
LCH.Clearnet [36]		X			X
JSCC [37]			X		X

c. Trade Repositories

The market for data services has evolved along similar lines. While there is currently no mandatory reporting requirement for the single-name CDS market, virtually all transactions are voluntarily reported to TIW, which maintains a legal record of transactions.[38] That there currently is a single dominant provider of recordkeeping services for security-based swaps is consistent with the presence of a natural monopoly for a service that involves a predominantly fixed cost investment with low marginal costs of operation.

There are currently no SDRs registered with the Commission.[39] Registration requirements are part of the new rules discussed in the SDR Adopting Release.[40] In the absence of SEC-registered SDRs, the analysis of the economic effects of the adopted rules and amendments discussed in this release on SDRs is informed by the experience of the CFTC-registered swap data repositories that operate in the swap market. The CFTC has provisionally registered four swap data repositories to accept transactions in swap credit derivatives.[41]

It is reasonable to estimate that a similar number of persons provisionally registered with the CFTC to service the equity and credit swap markets might seek to register with the Commission as SDRs, and that other persons could seek to register with both the CFTC and the Commission as swap data repositories and SDRs, respectively. There are economic incentives for the dual registration attributed to the fact that many of the market participants in the security-based swap market also participate in the swap market. Moreover, once a swap data repository is registered with the CFTC and the required infrastructure for regulatory reporting and public dissemination is in place, the marginal costs for a swap data repository to also register with the Commission as an SDR, adding products and databases and implementing modifications to account for differences between Commission and CFTC rules, will likely be lower than the initial cost of registration with the CFTC.

d. Vertical Integration of Security-Based Swap Market Infrastructure

The Commission has already observed vertical integration of swap market infrastructure: Clearing agencies have entered the market for record keeping services for swaps by provisionally registering themselves, or their affiliates, as swap data repositories with the CFTC. Under the CFTC swap reporting regime, two provisionally registered swap data repositories are, or are affiliated with, clearing agencies that clear swaps. These clearing agencies have adopted rules providing that they will satisfy their CFTC swap reporting obligations by reporting to their own, or their affiliated, swap data repository.[42] As a result, beta and gamma transactions and subsequent netting transactions that arise from the clearing process are reported by each of these clearing agencies to their associated swap data repositories.

4. Security-Based Swap Market: Market Participants and Dealing Structures

a. Market Centers

Financial groups engaged in security-based swap dealing activity operate in multiple market centers and carry out such activity with counterparties around the world.[43] Several commenters noted that many market participants that engage in dealing activity prefer to use traders and manage risk for security-based swaps in the jurisdiction where the underlier is traded.[44] Thus, although a significant amount of the dealing activity in security-based swaps on U.S. reference entities involves non-U.S. dealers, the Commission understands that these dealers tend to carry out much of the security-based swap trading and related risk-management activities in these security-based swaps within the United States.[45] Some dealers have explained that being able to centralize their trading, sales, risk management, and other activities related to U.S. reference entities in U.S. operations (even when the resulting transaction is booked in a foreign entity) improves the efficiency of their dealing business.[46]

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[32] *See* Securities Exchange Act Release No. 68080 (October 22, 2012), 77 FR at 66265 (November 2, 2012) (noting that economies of scale can result in natural monopolies). *See also* Craig Pirrong, "The Industrial Organization of Execution, Clearing and Settlement in Financial Markets," Working Paper (2007), available at *http://www.bauer.uh.edu/spirrong/Clearing_silos.pdf* (last visited May 25, 2016) (discussing the presence of economies of scale in central clearing).

[33] A current list of single-name and index CDS cleared by ICE Clear Credit is available at: *https://www.theice.com/publicdocs/clear_credit/ICE_Clear_Credit_Clearing_Eligible_Products.xls* (last visited May 25, 2016).

[34] A current list of single-name and index CDS cleared by ICE Clear Europe is available at: *https://www.theice.com/publicdocs/clear_europe/ICE_Clear_Europe_Cleared_Products_List.xlsx* (last visited on May 25, 2016).

[35] A current list of CDS cleared by CME is available at: *http://www.cmegroup.com/trading/cds/files/cleared-cds-product-specs.xls* (last visited May 25, 2016).

[36] A current list of single-name and index CDS cleared by LCH.Clearnet is available at: *http://www.lchclearnet.com/documents/731485/762470/cdsclear_product_list_oct_2015_.xlsx/20b23881-9973-4671-8e78-ee4cfc04b693* (last visited May 25, 2016).

[37] A current list of single-name and index CDS cleared by the Japanese Securities Clearing Corporation is available at: *http://www.jscc.co.jp/en/data/en/2015/05/Settlement_Prices.pdf* (last visited May 25, 2016).

[38] *See http://www.dtcc.com/derivatives-services/trade-information-warehouse* (last visited May 25, 2016) (describing the function and coverage of TIW).

[39] ICE Trade Vault, LLC, and DTCC Data Repository (U.S.) LLC ("DDR") each have filed an application with the Commission to register as an SDR. *See* Securities Exchange Act Release No. 77699 (April 22, 2016), 81 FR 25475 (April 28, 2016) (ICE Trade Vault); Securities Exchange Act Release No. 78216 (June 30, 2016), 81 FR at 44379 (July 7, 2016).

[40] *See* 80 FR at 14457–69.

[41] A list of swap data repositories provisionally registered with the CFTC is available at *http://sirt.cftc.gov/sirt/sirt.aspx?Topic=DataRepositories* (last visited May 25, 2016).

[42] *See* CME Clearing Rule 1001 (Regulatory Reporting of Swap Data); ICE Clear Credit Clearing Rule 211 (Regulatory Reporting of Swap Data).

Consistent with these operational concerns and the global nature of the security-based swap market, the available data appear to confirm that participants in this market are in fact active in market centers around the globe. Although, as noted above, the available data do not permit the Commission to identify the location of personnel in a transaction, TIW transaction records indicate that firms that are likely to be security-based swap dealers operate out of branch locations in key market centers around the world, including New York, London, Tokyo, Hong Kong, Chicago, Sydney, Toronto, Frankfurt, Singapore and the Cayman Islands.

Given these market characteristics and practices, participants in the security-based swap market may bear the financial risk of a security-based swap transaction in a location different from the location where the transaction is arranged, negotiated, or executed, or where economic decisions are made by managers on behalf of beneficial owners. And market activity may occur in a jurisdiction other than where the market participant or its counterparty books the transaction. Similarly, a participant in the security-based swap market may be exposed to counterparty risk from a counterparty located in a jurisdiction that is different from the market center or centers in which it participates.

b. Common Business Structures for Firms Engaged in Security-Based Swap Dealing Activity

A financial group that engages in a global security-based swap dealing business in multiple market centers may choose to structure its dealing business in a number of different ways. This structure, including where it books the transactions that constitute that business and how it carries out market-facing activities that generate those transactions, reflects a range of business and regulatory considerations, which each financial group may weigh differently.

A financial group may choose to book all of its security-based swap transactions, regardless of where the transaction originated, in a single, central booking entity. That entity generally retains the risk associated with that transaction, but it also may lay off that risk to another affiliate via a back-to-back transaction or an assignment of the security-based swap.[47] Alternatively, a financial group may book security-based swaps arising from its dealing business in separate affiliates, which may be located in the jurisdiction where it originates the risk associated with those security-based swaps, or alternatively, the jurisdiction where it manages that risk.[48] Some financial groups may book transactions originating in a particular region to an affiliate established in a jurisdiction located in that region.[49]

Regardless of where a financial group determines to book its security-based swaps arising out of its dealing activity, it is likely to operate offices that perform sales or trading functions in one or more market centers in other jurisdictions. Maintaining sales and trading desks in global market centers permits the financial group to deal with counterparties in that jurisdiction or in a specific geographic region, or to ensure that it is able to provide liquidity to counterparties in other jurisdictions, for example, when a counterparty's home financial markets are closed.[50] A financial group engaged in security-based swap dealing business also may choose to manage its trading book in particular reference entities or securities primarily from a trading desk that can take advantage of local expertise in such products or that can gain access to better liquidity, which may permit it to more efficiently price such products or to otherwise compete more effectively in the security-based swap market.[51] Some financial groups prefer to centralize risk management, pricing, and hedging for specific products with the personnel responsible for carrying out the trading of such products to mitigate operational risk associated with transactions in those products.

The financial group affiliate that books these transactions may carry out related market-facing activities, whether in its home jurisdiction or in a foreign jurisdiction, using either its own personnel or the personnel of an affiliated or unaffiliated agent. For example, the financial group may determine that another affiliate in the financial group employs personnel who possess expertise in relevant products or who have established sales relationships with key counterparties in a foreign jurisdiction, making it more efficient to use the personnel of the affiliate to engage in security-based swap dealing activity on its behalf in that jurisdiction.[52] In these cases, the affiliate that books these transactions and its affiliated agent may operate as an integrated dealing business, each performing distinct core functions in carrying out that business.

Alternatively, the financial group affiliate that books these transactions may in some circumstances determine to engage the services of an unaffiliated agent through which it can engage in dealing activity. For example, a financial group may determine that using an interdealer broker may provide an efficient means of participating in the interdealer market in its own, or in another, jurisdiction, particularly if it is seeking to do so anonymously or to take a position in products that trade relatively infrequently.[53] A financial group may also use unaffiliated agents that operate at its direction. Such an arrangement may be particularly valuable in enabling a financial group to service clients or access liquidity in jurisdictions in which it has no security-based swap operations of its own.

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[43] *See* U.S. Activity Adopting Release, 81 FR at 8603–604.

[44] *See* IIB Letter at 2; SIFMA/FSR Letter at 6; ISDA I at 5; MFA/AIMA Letter at 7, n. 34.

[45] *See* IIB Letter at 2; SIFMA/FSR Letter at 6; ISDA Letter at 5.

[46] *See id.*

[47] *See* U.S. Activity Adopting Release, 81 FR at 8604.

[48] *See id.*

[49] There is some indication that this booking structure is becoming increasingly common in the market. *See, e.g.,* "Regional swaps booking replacing global hubs," *Risk.net* (Sept. 4, 2015), available at: *http://www.risk.net/risk-magazine/feature/2423975/regional-swaps-booking-replacing-global-hubs.*

[50] These offices may be branches or offices of the booking entity itself, or branches or offices of an affiliated agent, such as, in the United States, a registered broker-dealer. *See* U.S. Activity Adopting Release, 81 FR at 8604–605.

[51] *See id.* at 8605.

[52] *See id.*

[53] The Commission understands that inter-dealer brokers may provide voice or electronic trading services that, among other things, permit dealers to take positions or hedge risks in a manner that preserves their anonymity until the trade is executed. These inter-dealer brokers also may play a particularly important role in facilitating transactions in less-liquid security-based swaps.

The Commission understands that financial group affiliates (whether affiliated with U.S.-based financial groups or not) that are established in foreign jurisdictions may use any of these structures to engage in dealing activity in the United States, and that they may seek to engage in dealing activity in the United States to transact with both U.S.-person and non-U.S.-person counterparties. In transactions with non-U.S.-person counterparties, these foreign affiliates may affirmatively seek to engage in dealing activity in the United States because the sales personnel of the non-U.S.-person dealer (or of its agent) in the United States have existing relationships with counterparties in other locations (such as Canada or Latin America) or because the trading personnel of the non-U.S. person dealer (or of its agent) in the United States have the expertise to manage the trading books for security-based swaps on U.S. reference securities or entities. The Commission understands that some of these foreign affiliates engage in dealing activity in the United States through their personnel (or personnel of their affiliates) in part to ensure that they are able to provide their own counterparties, or those of financial group affiliates in other jurisdictions, with access to liquidity (often in non-U.S. reference entities) during U.S. business hours, permitting them to meet client demand even when the home markets are closed. In some cases, such as when seeking to transact with other dealers through an interdealer broker, these foreign affiliates may act, in a dealing capacity, in the United States through an unaffiliated, third-party agent.

c. Current Estimates of Number of Security-Based Swap Dealers

Security-based swap activity is concentrated in a relatively small number of dealers, which already represent a small percentage of all market participants active in the security-based swap market.[54] Based on an analysis of 2015 data, the Commission's earlier estimates of the number of entities likely to register as security-based swap dealers remain largely unchanged.[55] Of the approximately 50 entities that the Commission estimates might register as security-based swap dealers, the Commission believes that it is reasonable to expect 22 to be non-U.S. persons.[56] Under the rules as they currently exist, the Commission identified approximately 170 entities engaged in single-name CDS activity, with all counterparties, of $2 billion or more. Of those entities, 104 are expected to incur assessment costs to determine whether they meet the definition of "security-based swap dealer." Approximately 47 of these entities are non-U.S. persons.[57]

Many of these dealers are already subject to other regulatory frameworks under U.S. law based on their role as intermediaries or on the volume of their positions in other products, such as swaps. Available data support the Commission's prior estimates, based on the Commission's experience and understanding of the swap and security-based swap market, that, of the 55 firms that might register as security-based swap dealers or major security-based swap participants, approximately 35 would also be registered with the CFTC as swap dealers or major swap participants.[58] Based on an analysis of TIW data and filings with the Commission, the Commission estimates that 16 market participants that will register as security-based swap dealers have already registered with the Commission as broker-dealers and are thus subject to Exchange Act and Financial Industry Regulatory Authority ("FINRA") requirements applicable to such entities. Finally, as the Commission discusses below, some dealers may be subject to similar requirements in one or more foreign jurisdictions.[59]

Finally, the Commission also notes that it has adopted rules for the registration of security-based swap dealers and major security-based swap participants, although market participants are not yet required to comply with those rules.[60] Thus, there are not yet any security-based swap dealers or major security-based swap participants registered with the Commission.

d. Arranging, Negotiating, and Executing Activity Using Personnel Located in a U.S. Branch or Office

Under rules recently adopted by the Commission as part of the U.S. Activity Adopting Release, non-U.S. persons will be required to apply transactions with other non-U.S. persons in connection with their dealing activity towards their *de minimis* thresholds when those transactions are arranged, negotiated, or executed by personnel located in a U.S. branch or office, or by personnel of an agent of such non-U.S. person located in a U.S. branch or office.[61] As a result of this requirement, certain market participants will likely incur costs associated with determining the location of relevant personnel who arrange, negotiate, or execute a transaction,[62] and, having determined the locations, these market participants will be able to identify those transactions that are arranged, negotiated, or executed by personnel located in a U.S. branch or office, or by personnel of an agent of such non-U.S. person located in a U.S. branch or office. The Commission estimated that an additional 20 non-U.S. persons, beyond the 56 identified under the Cross-Border Adopting Release, were likely to incur assessment costs in connection with the *de minimis* exception as a result of these rules.[63]

To estimate the number of unregistered foreign entities that arrange, negotiate, or execute security-based swap transactions using U.S. personnel in connection with their dealing activity for the purpose of this rulemaking, Commission staff used 2015 TIW single-name CDS transaction data to identify foreign entities that have three or more counterparties that are not recognized as dealers by ISDA and that traded less than $3 billion in notional volume and identified four entities that met these criteria. In 2015, these four entities were counterparties to 1,080 transactions in single-name CDS, referencing 186 reference entities, with a total notional volume of $5.2 billion. The Commission believes that these foreign dealing entities that are likely to remain unregistered engage in transactions in essentially the same products as foreign dealing entities that are likely to register as security-based swap dealers. The Commission staff observed in the 2015 data that foreign dealing entities that are likely to register as security-based swap dealers based on single-name CDS transaction activity in 2015 traded in 185 out of the 186 reference entities that the smaller foreign dealing entities had traded in.

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[54] *See* U.S. Activity Adopting Release, 81 FR at 8605.

[55] *See id.*

[56] These estimates are based on the number of accounts in TIW data with total notional volume in excess of *de minimis* thresholds, increased by a factor of two, to account for any potential growth in the security-based swap market, to account for the fact that the Commission is limited in observing transaction records for activity between non-U.S. persons that reference U.S. underliers, and to account for the fact that the Commission does not observe security-based swap transactions other than in single-name CDS. *See* U.S. Activity Adopting Release, 81 FR at 8605.

[57] *See id.*

[58] *See id.*

[59] *See id.* at 8605–606.

[60] In the SBS Entity Registration Adopting Release, the Commission established the compliance date for security-based swap dealer and major security-based swap participant registration (the "SBS entities registration compliance date") as the later of six months after the date of publication in the **Federal Register** of a final rule release adopting rules establishing capital, margin and segregation requirements for SBS entities; the compliance date of final rules establishing recordkeeping and reporting requirements for SBS entities; the compliance date of final rules establishing business conduct requirements under Exchange Act Sections 15F(h) and 15F(k); or the compliance date for final rules establishing a process for a registered SBS entities to make an application to the Commission to allow an associated person who is subject to a statutory disqualification to effect or be involved in effecting security-based swaps on the SBS entities' behalf. *See* 80 FR at 48964.

[61] *See* Rule 3a71–3(C) under the Exchange Act, 17 CFR 240.3a71–3(C).

[62] *See* U.S. Activity Adopting Release, 81 FR at 8627–28.

[63] *See id.* at 8627.

These smaller foreign dealing entities were counterparties to a very small number of security-based swaps involving foreign dealing entities engaging in U.S. activity. Using 2015 TIW data, the Commission estimates that foreign dealing entities that likely would register with Commission as security-based swap dealers based on their transaction activity in 2015, were counterparties to nearly all security-based swaps involving foreign dealing entities engaging in U.S. activity.[64]

5. Security-Based Swap Market: Levels of Security-Based Swap Trading Activity

As already noted, firms that act as dealers play a central role in the security-based swap market. Based on an analysis of 2015 single-name CDS data in TIW, accounts of those firms that are likely to exceed the security-based swap dealer *de minimis* thresholds and trigger registration requirements intermediated transactions with a gross notional amount of approximately $5.8 trillion, approximately 60% of which was intermediated by the top five dealer accounts.[65]

These dealers transact with hundreds or thousands of counterparties. Approximately 24% of accounts of firms expected to register as security-based dealers and observable in TIW have entered into security-based swaps with over 1,000 unique counterparty accounts as of year-end 2015.[66] Another 24% of these accounts transacted with 500 to 1,000 unique counterparty accounts; 16% transacted with 100 to 500 unique accounts; and 36% of these accounts intermediated swaps with fewer than 100 unique counterparties in 2015. The median dealer account transacted with 481 unique accounts (with an average of approximately 635 unique accounts). Non-dealer counterparties transacted almost exclusively with these dealers. The median non-dealer counterparty transacted with three dealer accounts (with an average of approximately four dealer accounts) in 2015.

Figure 2 below describes the percentage of global, notional transaction volume in North American corporate single-name CDS reported to TIW between January 2008 and December 2015, separated by whether transactions are between two ISDA-recognized dealers (interdealer transactions) or whether a transaction has at least one non-dealer counterparty.

Figure 2 also shows that the portion of the notional volume of North American corporate single-name CDS represented by interdealer transactions has remained fairly constant and that interdealer transactions continue to represent a significant majority of trading activity, even as notional volume has declined over the past seven years,[67] from more than $6 trillion in 2008 to less than $1.3 trillion in 2015.[68]

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[64] The Commission staff analysis of TIW transaction records indicates that approximately 99.72% of single-name CDS price-forming transactions and 99.73% of price-forming transaction volume in 2015 that involved foreign dealing entities involved a foreign dealing entity likely to register with the Commission as a security-based swap dealer based on its 2015 transaction activity.

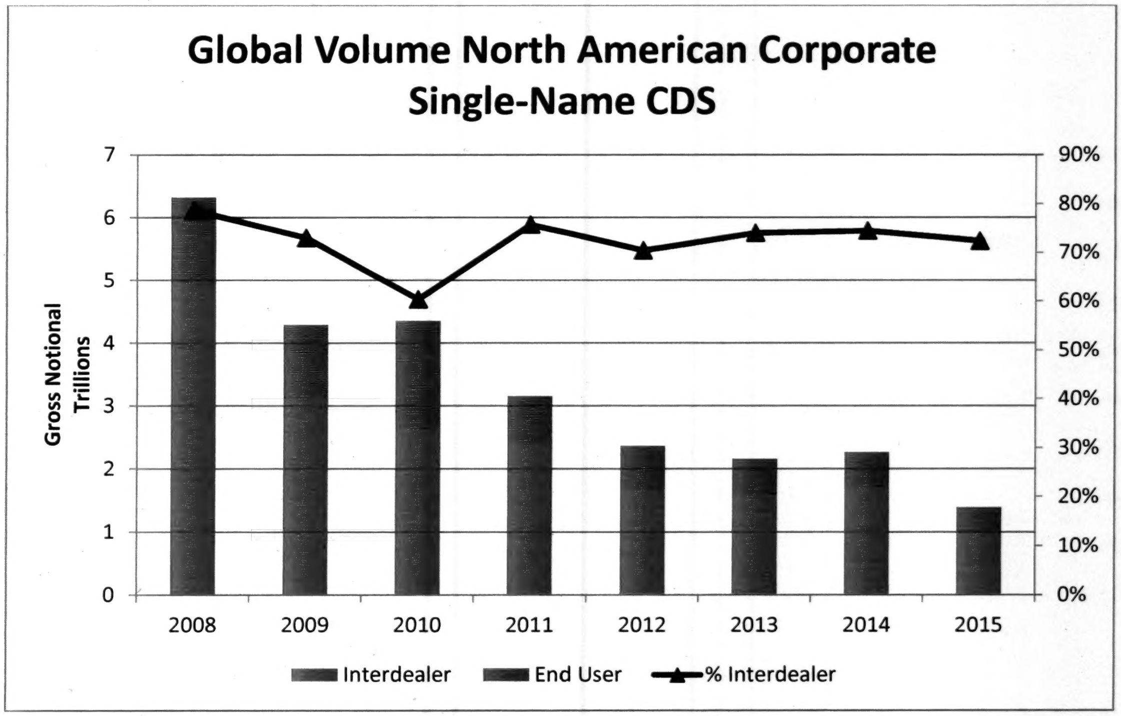
[65] The Commission staff analysis of TIW transaction records indicates that approximately 99% of single-name CDS price-forming transactions in 2015 involved an ISDA-recognized dealer.

[66] Many dealer entities and financial groups transact through numerous accounts. Given that individual accounts may transact with hundreds of counterparties, the Commission may infer that entities and financial groups may transact with at least as many counterparties as the largest of their accounts.

[67] The start of this decline predates the enactment of the Dodd-Frank Act and the proposal of rules thereunder, which is important to note for the purpose of understanding the economic baseline for this rulemaking.

[68] This estimate is lower than the gross notional amount of $5.8 trillion noted above as it includes only the subset of single-name CDS referencing North American corporate documentation. *See supra* note 65.

Figure 2: Global, notional trading volume in North American corporate single-name CDS by calendar year and the fraction of volume that is interdealer.



The high level of interdealer trading activity reflects the central position of a small number of dealers, each of which intermediates trades with many hundreds of counterparties. While the Commission is unable to quantify the current level of trading costs for single-name CDS, those dealers appear to enjoy market power as a result of their small number and the large proportion of order flow that they privately observe.

Against this backdrop of declining North American corporate single-name CDS activity, about half of the trading activity in North American corporate single-name CDS reflected in the set of data that the Commission analyzed was between counterparties domiciled in the United States and counterparties domiciled abroad, as shown in Figure 3 below. Using the self-reported registered office location of the TIW accounts as a proxy for domicile, the Commission estimates that only 12% of the global transaction volume by notional volume between 2008 and 2015 was between two U.S.-domiciled counterparties, compared to 48% entered into between one U.S.-domiciled counterparty and a foreign-domiciled counterparty and 40% entered into between two foreign-domiciled counterparties.[69]

If the Commission considers the number of cross-border transactions instead from the perspective of the domicile of the corporate group (*e.g.*, by classifying a foreign bank branch or foreign subsidiary of a U.S. entity as domiciled in the United States), the percentages shift significantly. Under this approach, the fraction of transactions entered into between two U.S.-domiciled counterparties increases to 33%, and to 52% for transactions entered into between a U.S.-domiciled counterparty and a foreign-domiciled counterparty. By contrast, the proportion of activity between two foreign-domiciled counterparties drops from 40% to 16%. This change in respective shares based on different classifications suggests that the activity of foreign subsidiaries of U.S. firms and foreign branches of U.S. banks accounts for a higher percentage of security-based swap activity than U.S. subsidiaries of foreign firms and U.S. branches of foreign banks. It also demonstrates that financial groups based in the United States are involved in an overwhelming majority (approximately 85%) of all reported transactions in North American corporate single-name CDS.

Financial groups based in the United States are also involved in a majority of interdealer transactions in North American corporate single-name CDS. Of transactions on North American corporate single-name CDS between two ISDA-recognized dealers and their branches or affiliates, 93% of transaction notional volume involved at least one account of an entity with a U.S. parent.

The Commission notes, in addition, that a significant majority of North American corporate single-name CDS transactions occur in the interdealer market or between dealers and foreign non-dealers, with the remaining (and much smaller) portion of the market consisting of transactions between dealers and U.S.-person non-dealers. Specifically, 74% of North American corporate single-name CDS transactions involved either two ISDA-recognized dealers or an ISDA-recognized dealer and a foreign non-dealer. Approximately 16.5% of such transactions involved an ISDA-recognized dealer and a U.S.-person non-dealer.

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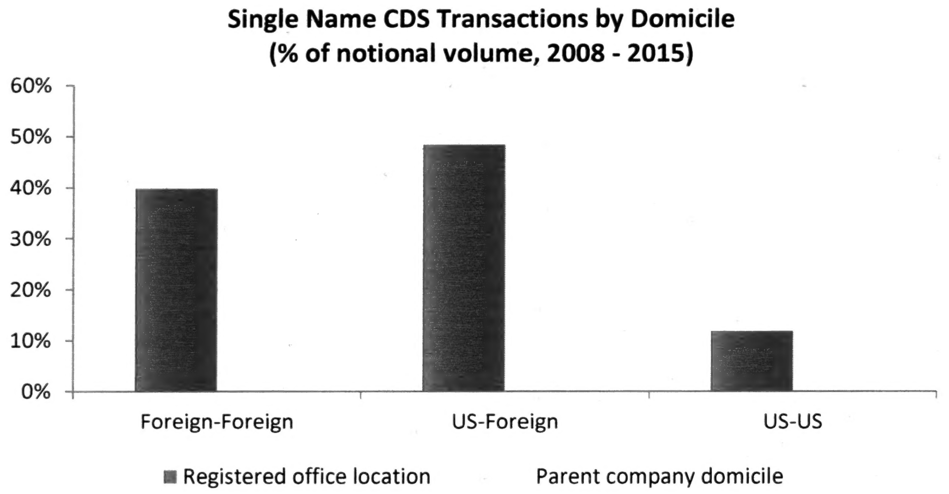
[69] For purposes of this discussion, the Commission has assumed that the registered office location reflects the place of domicile for the fund or account, but the Commission notes that this domicile does not necessarily correspond to the location of an entity's sales or trading desk. *See* U.S. Activity Adopting Release, 81 FR at 8607, n. 83.

Figure 3: The fraction of notional volume in North American corporate single-name CDS between (1) two U.S.-domiciled accounts; (2) one U.S.-domiciled account and one non-U.S.-domiciled account; and (3) two non-U.S.-domiciled accounts, computed from January 2008 through December 2015.



6. Global Regulatory Efforts

In 2009, the G20 Leaders—whose membership includes the United States, 18 other countries, and the European Union—addressed global improvements in the OTC derivatives markets. They expressed their view on a variety of issues relating to OTC derivatives contracts. In subsequent summits, the G20 Leaders have returned to OTC derivatives regulatory reform and encouraged international consultation in developing standards for these markets.[70]

Foreign legislative and regulatory efforts have focused on five general areas: moving OTC derivatives onto organized trading platforms, requiring central clearing of OTC derivatives, requiring post-trade reporting of transaction data for regulatory purposes and public dissemination of anonymized versions of such data, establishing or enhancing capital requirements for non-centrally cleared OTC derivatives transactions, and establishing or enhancing margin and other risk mitigation requirements for non-centrally cleared OTC derivatives transactions. The rules being adopted in this release will affect a person's obligations with respect to post-trade reporting of transaction data for public dissemination and regulatory purposes under Regulation SBSR.

Foreign jurisdictions have been actively implementing regulations of the OTC derivatives markets. Regulatory transaction reporting requirements are in force in a number of jurisdictions, including the European Union, Hong Kong SAR, Japan, Australia, Brazil, Canada, China, India, Indonesia, South Korea, Mexico, Russia, Saudi Arabia, and Singapore; other jurisdictions are in the process of proposing legislation and rules to implement these requirements.[71] The CFTC, the 13 Canadian provinces and territories, the European Union, and Japan have adopted requirements to publicly disseminate transaction-level data about OTC derivatives transactions. In addition, a number of foreign jurisdictions have initiated the process of implementing margin and other risk mitigation requirements for non-centrally cleared OTC derivatives transactions.[72] Several jurisdictions have also taken steps to implement the Basel III recommendations governing capital requirements for financial entities, which include enhanced capital charges for non-centrally cleared OTC derivatives transactions.[73] There has been limited progress in moving OTC derivatives onto organized trading platforms among G20 countries. The CFTC mandated the trading of certain interest rate swaps and index CDS on CFTC-regulated SEFs in 2014. Japan implemented a similar requirement for a subset of Yen-denominated interest rate swaps in September 2015. The European Union has adopted legislation that addresses trading OTC derivatives on regulated trading platforms, but has not mandated specific OTC derivatives to trade on these platforms. This legislation also should promote post-trade public transparency in OTC derivatives markets by requiring the price, volume, and time of derivatives transactions conducted on these regulated trading platforms to be made public in as close to real time as technically possible.[74]

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[70] *See, e.g.,* G20 Leaders' Final Declaration (November 2011), paragraph 24, available at: *http://www.g20.utoronto.ca/2011/2011-cannes-declaration-111104-en.html* (last visited on May 25, 2016).

[71] *See* Financial Stability Board, OTC Derivatives Market Reforms Tenth Progress Report on Implementation (November 2015), available at *http://www.fsb.org/wp-content/uploads/OTC-Derivatives-10th-Progress-Report.pdf* (last visited on May 25, 2016). The Financial Stability Board's report on a peer review of trade reporting confirmed that most Financial Stability Board member jurisdictions have trade reporting requirements in place. *See* Financial Stability Board, Thematic Review on OTC Derivatives Trade Reporting (November 2015), available at *http://www.fsb.org/wp-content/uploads/Peer-review-on-trade-reporting.pdf* (last visited on May 25, 2016).

[72] In November 2015, the Financial Stability Board reported that 12 member jurisdictions participating in its tenth progress report on OTC derivatives market reforms had in force a legislative framework or other authority to require exchange of margin for non-centrally cleared transactions and had published implementing standards or requirements for consultation or proposal. A further 11 member jurisdictions had a legislative framework or other authority in force or published for consultation or proposal. *See* Financial Stability Board, OTC Derivatives Market Reforms Tenth Progress Report on Implementation (November 2015), available at *http://www.financialstabilityboard.org/wp-content/uploads/OTC-Derivatives-10th-Progress-Report.pdf (last visited on May 25, 2016).*

[73] In November 2015, the Financial Stability Board reported that 18 member jurisdictions participating in its tenth progress report on OTC derivatives market reforms had in force standards or requirements covering more than 90% of transactions that require enhanced capital charges for non-centrally cleared transactions. A further

B. Economic Considerations

In the Regulation SBSR Adopting Release, the Commission highlighted certain overarching effects on the security-based swap market that it believes will result from the adoption of Regulation SBSR. These benefits could include, generally, improved market quality, improved risk management, greater efficiency, and improved oversight by the Commission and other relevant authorities.[75] Regulation SBSR requires market participants to make infrastructure investments in order to report security-based swap transactions to registered SDRs, and for SDRs to make infrastructure investments to receive and store that transaction data and to publicly disseminate transaction data in a manner required by Rule 902 of Regulation SBSR.

The amendments to Regulation SBSR being adopted today will, among other things, impose certain requirements on the platforms,[76] registered clearing agencies, and registered SDRs that constitute infrastructure for the security-based swap market and provide services to counterparties who participate in security-based swap transactions. The adopted amendments and the guidance provided will affect the manner in which these infrastructure providers compete with one another and exercise market power over security-based swap counterparties. In turn, there will be implications for the security-based swap counterparties who utilize these infrastructure providers and the security-based swap market generally.

In addition, the Commission is adopting regulatory reporting and public dissemination requirements under Regulation SBSR for certain types of cross-border security-based swaps not currently addressed in Regulation SBSR. Subjecting additional types of security-based swaps to regulatory reporting and public dissemination will affect the overall costs and benefits associated with Regulation SBSR and have implications for transparency, competition, and liquidity provision in the security-based swap market.

1. Security-Based Swap Market Infrastructure

Title VII requires the Commission to create a new regulatory regime for the security-based swap market that, among other things, includes trade execution, central clearing, and reporting requirements aimed at increasing transparency and customer protection as well as mitigating the risk of financial contagion.[77] These new requirements, once implemented, might require market participants, who may have previously engaged in bilateral transaction activity without any need to engage third-party service providers, to interface with platforms, registered clearing agencies, and registered SDRs.

As a general matter, rules that require regulated parties to obtain services can have a material impact on the prices of those services in the absence of a competitive market for those services. In particular, if service providers are monopolists or otherwise have market power, requiring market participants to obtain their services can potentially allow the service providers to increase the profits that they earn from providing the required services.[78] Because Title VII requires the Commission to implement rules requiring market participants to use the services provided by platforms,[79] registered clearing agencies,[80] and registered SDRs,[81] these requirements could reduce the sensitivity of demand to changes in prices or quality of the services of firms that create and develop security-based swap market infrastructure. As such, should security-based swap infrastructure providers–such as platforms, registered clearing agencies, and registered SDRs–enjoy market power, they might be able to change their prices or service quality without a significant effect on demand for their services. In turn, these changes in prices or quality could have negative effects on activity in the security-based swap market.

As discussed in Section XIII, *infra*, the amendments to Regulation SBSR being adopted today could have an impact on the level of competition among suppliers of trade reporting services and affect the relative bargaining power of suppliers and consumers in determining the prices of those services. In particular, when the supply of trade reporting services is concentrated among a small number of firms, consumers of these services have few alternative suppliers from which to choose. Such an outcome could limit the incentives to produce more efficient trade reporting processes and services and could, in certain circumstances, result in less security-based swap transaction activity than would otherwise be optimal. In the case of security-based swap transaction activity, welfare losses could result from higher costs to counterparties for hedging financial or commercial risks.

2. Competition Among Security-Based Swap Infrastructure Providers

As noted above, the Commission recognizes how regulatory requirements may affect the demand for services provided by platforms, registered clearing agencies, and SDRs, and, in turn, the ability of these entities to exercise their market power. The Commission's economic analysis of the amendments adopted today considers how the competitive landscape for platforms, registered clearing agencies, and registered SDRs might affect the market power of these entities and hence the level and allocation of costs related to regulatory requirements. Some of the factors that may influence this competitive landscape have to do with the nature of trade reporting and are unrelated to regulation, while others

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three member jurisdictions had a legislative framework or other authority in force and had adopted implementing standards or requirements that were not yet in force. An additional three member jurisdictions had a legislative framework or other authority in force or published for consultation or proposal. *See* Financial Stability Board, OTC Derivatives Market Reforms Tenth Progress Report on Implementation (November 2015), available at *http://www.financialstabilityboard.org/wp-content/uploads/OTC-Derivatives-10th-Progress-Report.pdf (last visited on May 25, 2016).*

[74] *See* Regulation (EU) No 600/2014 of the European Parliament and of the Council of 15 May 2014 on markets in financial instruments and amending Regulation (EU) no 648/2012), available at: *http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32014R0600&from=EN (last visited on May 25, 2016).*

[75] *See* Regulation SBSR Adopting Release, 80 FR at 14699–705.

[76] A platform is a national securities exchange or security-based swap execution facility that is registered or exempt from registration. *See* Rule 900(v), 17 CFR 242.900(v).

[77] *See* Cross-Border Adopting Release, 79 FR at 47285.

[78] These effects, as they relate specifically to the rules and amendments, as well as alternative approaches, are discussed in Section XIII, *infra*.

[79] *See* 15 U.S.C. 78c-3(h)(1).

[80] *See* 15 U.S.C. 78c-3(a)(1).

[81] *See* 15 U.S.C. 78m(m)(1)(G).

may be a result of, or influenced by, the rules that the Commission is adopting in this release. To the extent that the adopted rules inhibit competition among infrastructure providers, they could result in fees charged to counterparties that deviate from the underlying costs of providing services.

As a general matter, trade execution, clearing, and reporting services are likely to be concentrated among a small number of providers. For example, SDRs and clearing agencies must make significant infrastructure and human capital investments to enter their respective markets, but once these start-up costs are incurred, the addition of data management by SDRs or transaction clearing services by clearing agencies is likely to occur at low marginal costs. As a result, the per-transaction cost to provide infrastructure services quickly falls for SDRs and clearing agencies as their customer base grows, because they are able to amortize the fixed costs associated with serving counterparties over a larger number of transactions. These economies of scale would be expected to favor incumbent service providers who can leverage their market position to discourage entry by potential new competitors that face significant fixed costs to enter the market. As a result, the markets for clearing services and SDR services are likely to be dominated by a small number of firms that each have large market share, which is borne out in the current security-based swap market.[82]

Competition among registered clearing agencies and registered SDRs could also be influenced by the fact that security-based swap market participants incur up-front costs for each connection that they establish with an SDR or clearing agency. If these costs are sufficiently high, an SDR or clearing agency could establish itself as an industry leader by "locking-in" customers who are unwilling or unable to make a similar investment for establishing a connection with a competitor.[83] An SDR or clearing agency attempting to enter the market or increase market share would have to provide services valuable enough, or set fees low enough, to offset the costs of switching from a competitor. In this way, costs to security-based swap market participants of interfacing with market infrastructure could serve as a barrier to entry for firms that would like to provide market infrastructure services provided by SDRs and clearing agencies.

The rules adopted today might also influence the competitive landscape for firms that provide security-based swap market infrastructure. Fundamentally, requiring the reporting of security-based swap transactions to SDRs creates an inelastic demand for reporting services that would not be present if not for regulation. This necessarily reduces a counterparty's ability to bargain with infrastructure service providers over price or service because the option of not reporting is unavailable. Moreover, infrastructure requirements imposed by Title VII regulation will increase the fixed costs of an SDR operating in the security-based swap market and increase the barriers to entry into the market, potentially discouraging firms from entering the market for SDR services. For example, under Rule 907, as adopted, registered SDRs are required to establish and maintain certain written policies and procedures. The Commission estimated that this requirement will impose initial costs on each registered SDR of approximately $12,250,000.[84]

The rules adopted today might also affect the competitive landscape by increasing the incentives for security-based swap infrastructure service providers to integrate horizontally or vertically. As a general matter, firms engage in horizontal integration when they expand their product offerings to include similar goods and services or to acquire competitors. For example, swap data repositories that presently serve the swap market might horizontally integrate by offering similar services in the security-based swap market. Firms vertically integrate by entering into businesses that supply the market that they occupy ("backward vertical integration") or by entering into businesses that they supply ("forward vertical integration").

As discussed in more detail in Section XIII(A), *infra,* while adopting a reporting methodology that assigns reporting responsibilities to registered clearing agencies, which will hold the most complete and accurate information for cleared transactions, could minimize potential data discrepancies and errors, rules that give registered clearing agencies discretion over where to report transaction data could provide incentives for registered clearing agencies to create affiliate SDRs and compete with other registered SDRs for post-trade reporting services. The cost to a clearing agency of entering the market for SDR services is likely to be low, given that many of the infrastructure requirements for entrant SDRs are shared by clearing agencies. Clearing agencies already have the infrastructure necessary for capturing transaction records from clearing members and might be able to leverage that preexisting infrastructure to provide services as an SDR at lower incremental cost than other new SDRs. Because all clearing transactions, like all other security-based swaps, must be reported to a registered SDR, there would be a set of potentially captive transactions that clearing agencies could initially use to vertically integrate into SDR services.[85]

Entry into the SDR market by registered clearing agencies could potentially lower the cost of SDR services if clearing agencies are able to transmit data to an affiliated SDR at a lower cost relative to transmitting the same data to an independent SDR. The Commission believes that this is likely to be true for clearing transactions, given that the clearing agency and the affiliated SDR would have greater control over the reporting process relative to sending clearing transaction data to an independent SDR. Even if registered clearing agencies did not enter the market for SDR services, their ability to pursue a vertical integration strategy could motivate incumbent SDRs to offer competitive service models.

However, the Commission recognizes that the entry of clearing-agency-affiliated SDRs might not necessarily result in increased competition among SDRs or result in lower costs for SDR services. In an environment where registered clearing agencies with affiliated SDRs have discretion to send their clearing transaction data to their affiliates, security-based swap market participants who wish to submit their transactions to clearing may have reduced ability to direct the reporting of the clearing transaction to an independent SDR. As a result, clearing-agency-affiliated SDRs would not directly compete with independent SDRs on the basis of price or quality, because they inherit their clearing agency affiliate's market share. This might allow clearing agency incumbents to exercise market power through their affiliated SDRs relative to independent SDRs.

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[82] *See supra* Section II(A).

[83] *See* Joseph Farrell and Paul Klemperer, "Coordination and Lock-in: Competition with Switching Costs and Network Effects," in *Handbook of Industrial Organization,* Mark Armstrong and Robert Porter (ed.) (2007), at 1972. The authors describe how switching costs affect entry, noting that, on one hand, "switching costs hamper forms of entry that must persuade customers to pay those costs" while, on the other hand, if incumbents must set a single price for both new and old customers, a large incumbent might focus on harvesting its existing customer base, ceding new customers to the entrant. In this case, a competitive market outcome would be characterized by prices for services that equal the marginal costs associated with providing services to market participants. This is because, in a competitive market with free entry and exit of firms, a firm that charges a price that is higher than marginal cost would lose sales to existing firms or entrants that are willing to provide the same service at a lower price. Such price competition prevents firms from charging prices that are above marginal costs.

[84] *See* Regulation SBSR Adopting Release, 80 FR at 14718, n. 1343.

[85] A registered clearing agency expanding to provide SDR services is an example of forward vertical integration. In the context of the rules adopted today, SDRs "consume" the data supplied by registered clearing agencies. Clearing agencies engage in forward vertical integration by creating or acquiring the SDRs that consume the data that they produce as a result of their clearing business.

3. Security-Based Swaps Trading by Non-U.S. Persons Within the United States

Several broad economic considerations have informed the Commission's approach to identifying transactions between two non-U.S. persons that should be subject to certain Title VII requirements. The Commission has taken into account the potential impact that rules already adopted as part of the Regulation SBSR Adopting Release might have on competition between U.S. persons and non-U.S. persons when they engage in security-based swap transactions with non-U.S. persons, along with the implications of these competitive frictions for the ability of market participants to obtain liquidity in a market that is predominantly over-the-counter. In particular, competitive disparities could arise between U.S. dealing entities and foreign dealing entities[86] using personnel located in a U.S. branch or office when serving unregistered non-U.S. counterparties. In the absence of the rules adopted today, U.S. dealing entities and their agents would bear the costs associated with regulatory reporting and public dissemination requirements when trading with unregistered non-U.S. counterparties, while foreign dealing entities that use U.S.-based personnel to trade with the same unregistered non-U.S. counterparties would not bear such regulatory costs if these foreign dealing entities are not subject to comparable regulatory requirements in their home jurisdictions. Thus, these foreign dealing entities could offer liquidity at a lower cost to unregistered non-U.S. persons thereby gaining a competitive advantage over U.S. dealing entities.

Competitive disparities could also arise between U.S. persons and non-U.S. persons that trade with foreign dealing entities that use U.S. personnel to arrange, negotiate, or execute security-based swap transactions.[87] A transaction between an unregistered U.S. person and a foreign dealing entity that uses U.S. personnel to arrange, negotiate, or execute the transaction is subject to regulatory reporting and public dissemination under existing Rule 908(a)(1)(i). In the absence of newly adopted Rule 908(a)(1)(v), a transaction between an unregistered non-U.S. person and the foreign dealing entity engaging in ANE activity would not be subject to Regulation SBSR. This could create a competitive advantage for unregistered non-U.S. persons over similarly situated U.S. persons when unregistered non-U.S. persons trade with foreign dealing entities that engage in ANE activity. Such a foreign dealing entity might be able to offer liquidity to an unregistered non-U.S. person at a lower price than to an unregistered U.S. person, because the foreign dealing entity that is engaging in ANE activity would not have to embed the potential costs of regulatory reporting and public dissemination into the price offered to the unregistered non-U.S. counterparty. By contrast, the price offered by that foreign dealing entity to an unregistered U.S. counterparty likely would reflect these additional costs.

The Commission acknowledges, however, that applying Title VII rules based on the location of personnel who engage in relevant conduct could provide incentives for these foreign dealing entities to restructure their operations to avoid triggering requirements under Regulation SBSR. For example, a foreign dealing entity could restrict its U.S. personnel from intermediating transactions with non-U.S. persons or use agents who are located outside the United States when engaging in security-based swap transactions with non-U.S. persons.

In addition, disparate treatment of transactions depending on whether they are arranged, negotiated, or executed by personnel located in a U.S. branch or office could create fragmentation among agents that may seek to provide services to foreign dealing entities. To the extent that using agents with personnel located in a U.S. branch or office might result in regulatory costs being imposed on foreign dealing entities, such entities might prefer and primarily use agents located outside the United States, while U.S. dealers might continue to use agents located in the United States.

III. Reporting by Registered Clearing Agencies

A. Background

Section 13(m)(1)(F) of the Exchange Act[88] provides that parties to a security-based swap (including agents of parties to a security-based swap) shall be responsible for reporting security-based swap transaction information to the appropriate registered entity in a timely manner as may be prescribed by the Commission. Section 13(m)(1)(G) of the Exchange Act[89] provides that each security-based swap (whether cleared or uncleared) shall be reported to a registered SDR. Section 13A(a)(3) of the Exchange Act[90] specifies the party obligated to report a security-based swap that is not accepted for clearing by any clearing agency or derivatives clearing organization. To implement these statutory provisions, the Commission in February 2015 adopted Rule 901(a) of Regulation SBSR, which designates the persons who must report all security-based swaps except: (1) Clearing transactions;[91] (2) security-based swaps that are executed on a platform and that will be submitted to clearing; (3) transactions where there is no U.S. person, registered security-based swap dealer, or registered major security-based swap participant on either side; and (4) transactions where there is no registered security-based swap dealer or registered major security-based swap participant on either side and there is a U.S. person on only one side ("covered transactions"). This section addresses reporting duties for clearing transactions—*i.e.,* the security-based swaps in category (1) above.[92]

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[86] Throughout this release, a "dealing entity" refers to an entity that engages in security-based swap dealing activity regardless of whether the volume of such activity exceeds the *de minimis* threshold established by the Commission that would cause the entity to be a "security-based swap dealer" and thus require the entity to register with the Commission as a security-based swap dealer.

[87] Throughout this release, a security-based swap transaction involving a non-U.S.-person counterparty that, in connection with its dealing activity, has arranged, negotiated, or executed using its personnel located in a U.S. branch or office, or the personnel of its agent located in a U.S. branch or office, is referred to as an "ANE transaction"; the arrangement, negotiation, and/or execution of such a security-based swap by personnel of a non-U.S. person located in a U.S. branch or office, or by the personnel of its agent located in a U.S. branch or office are referred to as "ANE activities" or "engaging in ANE activity"; and the personnel located in the U.S. branch or office of the foreign dealing entity, or (if applicable) the personnel of its agent located in a U.S. branch or office, are referred to as "U.S. personnel."

[88] 15 U.S.C. 78m(m)(1)(F).

[89] 15 U.S.C. 78m(m)(1)(G).

[90] 15 U.S.C. 78m–1(a)(3).

[91] Rule 900(g) defines "clearing transaction" as "a security-based swap that has a registered clearing agency as a direct counterparty." This definition describes security-based swaps that arise when a registered clearing agency accepts a security-based swap for clearing as well as security-based swaps that arise as part of a clearing agency's internal processes, including those used to establish prices for cleared products and those resulting from netting other clearing transactions of the same product in the same account into a new open position. *See* Regulation SBSR Adopting Release, 80 FR at 14599.

1. Clearing Process for Security-Based Swaps

As discussed in the Regulation SBSR Adopting Release and the Regulation SBSR Proposed Amendments Release, two models of clearing—an agency model and a principal model—are currently used in the swap markets.[93] In the agency model, which predominates in the United States, a swap that is submitted to clearing—typically referred to in the industry as an "alpha"—is, if accepted by the clearing agency, terminated and replaced with two new swaps, known as the "beta" and "gamma." One of the direct counterparties[94] to the alpha becomes a direct counterparty to the beta, the other direct counterparty to the alpha becomes a direct counterparty to the gamma, and the clearing agency becomes a direct counterparty to each of the beta and the gamma.[95] This release uses the terms "alpha," "beta," and "gamma" in the same way that the Commission understands they are used in the agency model of clearing in the U.S. swap market. As noted in the Regulation SBSR Adopting Release, an alpha is not a "clearing transaction" under Regulation SBSR, even though it is submitted for clearing, because it does not have a registered clearing agency as a direct counterparty.[96]

2. Proposed Rules and General Summary of Comments

In the Regulation SBSR Proposed Amendments Release, the Commission proposed a new paragraph (a)(2)(i) of existing[97] Rule 901(a), which would designate a registered clearing agency as the reporting side for all clearing transactions to which it is a counterparty. In its capacity as the reporting side, the registered clearing agency would be permitted to select the registered SDR to which it reports.[98]

The Commission also proposed certain rules that would specify the reporting requirements for life cycle events attendant to the clearing process. The determination by a registered clearing agency of whether or not to accept an alpha for clearing is a life cycle event of the alpha.[99] Existing paragraph (i) of Rule 901(e)(1) generally requires the reporting side for a security-based swap to report a life cycle event of that security-based swap, "except that the reporting side shall not report whether or not a security-based swap has been accepted for clearing." Under existing Rule 901(e)(2), a life cycle event must be reported "to the entity to which the original security-based swap transaction was reported." In the Regulation SBSR Proposed Amendments Release, the Commission proposed a new paragraph (ii) of Rule 901(e)(1) that would require a registered clearing agency to report to the registered SDR that received or will receive the transaction report of the alpha (the "alpha SDR") whether or not it has accepted an alpha security-based swap for clearing.[100] The Commission also proposed to amend the definition of "participant" in existing Rule 900(u) to include a registered clearing agency that is required to report whether or not it accepts an alpha for clearing.[101]

If the registered clearing agency does not know the identity of the alpha SDR, the registered clearing agency would be unable to report to the alpha SDR whether or not it accepted the alpha transaction for clearing, as required by proposed Rule 901(e)(1)(ii). Therefore, the Commission proposed a new paragraph (3) of Rule 901(a), which would require the platform or reporting side for a security-based swap that has been submitted to clearing to promptly provide the relevant registered clearing agency with the identity of the alpha SDR and the transaction ID of the alpha transaction that will be or has been submitted to clearing.[102]

The Commission requested and received comment on a wide range of issues related to these proposed amendments. Four commenters generally supported the Commission's proposal to require the registered clearing agency to report clearing transactions and to allow it to select the SDR to which it reports.[103] One of these commenters noted that a clearing agency is "the sole party who holds the complete and accurate record of transactions and positions" for clearing transactions.[104] Another commenter agreed, noting that alternative reporting workflows "could require a person who does not have information about [a] clearing transaction at the time of its creation to report that transaction."[105] The commenter expressed the view that the Commission's proposal for reporting clearing transactions "is simple in that the same party in each and every transaction will be the party with the reporting requirement," and that this approach would eliminate confusion "as to who has the obligation to report the initial trades and different life-cycle events."[106] Two commenters expressed the view that clearing agencies can leverage existing reporting processes and the existing infrastructure that they have in place with market participants and vendors to report clearing transactions.[107] A third commenter observed that requiring clearing agencies to report clearing transactions would be "efficient, cost effective and promote[ ] global data consistency," because clearing agencies already report transactions under swap data reporting rules established by the CFTC and certain foreign jurisdictions, such as the European Union and Canada.[108]

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[92] Security-based swaps in category (2) are discussed in Section IV, *infra.* Security-based swaps in categories (3) and (4) are discussed in Section IX, *infra.*

[93] *See* Regulation SBSR Adopting Release, 80 FR at 14599; Regulation SBSR Proposed Amendments Release, 80 FR at 14742–43.

[94] Existing Rule 900(k) defines "direct counterparty" as "a person that is a primary obligor on a security-based swap."

[95] If both direct counterparties to the alpha are clearing members, the direct counterparties would submit the transaction to the clearing agency directly and the resulting beta would be between the clearing agency and one clearing member, and the gamma would be between the clearing agency and the other clearing member. The Commission understands, however, that, if the direct counterparties to the alpha are a clearing member and a non-clearing member (a "customer"), the customer's side of the trade would be submitted for clearing by a clearing member acting on behalf of the customer. When the clearing agency accepts the alpha for clearing, one of the resulting swaps—in this case, assume the beta—would be between the clearing agency and the customer, with the customer's clearing member acting as guarantor for the customer's trade. The other resulting swap—the gamma—would be between the clearing agency and the clearing member that was a direct counterparty to the alpha. *See, e.g.,* Byungkwon Lim and Aaron J. Levy, "Contractual Framework for Cleared Derivatives: The Master Netting Agreement Between a Clearing Customer Bank and a Central Counterparty," 10 Pratt's J. of Bankr. Law 509, 515–517 (LexisNexis A.S. Pratt) (describing the clearing model for swaps in the United States); LCH.Clearnet Letter at 2 (generally concurring with the Commission's depiction of the agency model of clearing).

[96] *See* 80 FR at 14599. This release does not address the application of Section 5 of the Securities Act of 1933, 15 U.S.C. 77a *et seq.* ("Securities Act"), to security-based swap transactions that are intended to be submitted to clearing (*i.e.,* alphas, in the agency model of clearing). Rule 239 under the Securities Act, 17 CFR 230.239, provides an exemption for certain security-based swap transactions involving an eligible clearing agency from all provisions of the Securities Act, other than anti-fraud provisions of Section 17(a) of the Securities Act. This exemption does not apply to security-based swap transactions not involving an eligible clearing agency, including a transaction that is intended to be submitted to clearing, regardless of whether the security-based swaps subsequently are cleared by an eligible clearing agency. *See* Exemptions for Security-Based Swaps Issued By Certain Clearing Agencies, Securities Act Release No. 33–9308 (March 30, 2012), 77 FR 20536 (April 5, 2012).

[97] Throughout this release, the Commission distinguishes "existing" provisions of Regulation SBSR—*i.e.,* provisions of Regulation SBSR that the Commission adopted in the Regulation SBSR Adopting Release in February 2015—from provisions that the Commission is adopting in this release.

[98] *See* Regulation SBSR Proposed Amendments Release, 80 FR at 14746–47.

[99] *See id.,* 80 FR at 14746, 14748. A life cycle event is, with respect to a security-based swap, any event that would result in a change in the information reported to a registered security-based swap data repository under Rule 901(c), 901(d), or 901(i), including an assignment or novation of the security-based swap; a partial or full termination of the security-based swap; a change in the cash flows originally reported; for a security-based swap that is not a clearing transaction, any change to the title or date of any master agreement, collateral agreement, margin agreement, or any other agreement incorporated by reference into the security-based swap contract; or a corporate action affecting a security or securities on which the security-based swap is based (*e.g.,* a merger, dividend, stock split, or bankruptcy). Notwithstanding the above, a life cycle event shall not include the scheduled expiration of the security-based swap, a previously described and anticipated interest rate adjustment (such as a quarterly interest rate adjustment), or other event that does not result in any change to the contractual terms of the security-based swap. *See* 17 CFR 242.900(q).

[100] *See* Regulation SBSR Proposed Amendments Release, 80 FR at 14748.

[101] *See id.* at 14751.

[102] *See id.* at 14748.

[103] *See* LCH.Clearnet Letter at 3; Better Markets Letter at 2; ISDA/SIFMA Letter at 24; ICE Letter at 1, 5.

[104] ICE Letter at 1, 3 (arguing that no person other than a clearing agency has complete information

However, one commenter opposed assigning the reporting duty to the registered clearing agency, arguing instead that the reporting side for the alpha transaction should be the reporting side for any subsequent clearing transactions.[109] Another commenter expressed support for the Commission's proposal to require registered clearing agencies to report betas and gammas, but disagreed with the Commission's proposal to permit registered clearing agencies to choose the registered SDR that receives these reports.[110]

B. Discussion and Final Rules

After careful consideration of the comments, the Commission is adopting paragraph (2)(i) of Rule 901(a) as proposed. As a result, a registered clearing agency is the reporting side for all clearing transactions to which it is a counterparty.[111] In its capacity as the reporting side, the registered clearing agency is permitted to select the registered SDR to which it reports.

The Commission believes that, because a registered clearing agency creates the clearing transactions to which it is a counterparty, the registered clearing agency is in the best position to provide complete and accurate information to a registered SDR about the clearing transactions resulting from the security-based swaps that it clears. Two commenters noted that swap clearing agencies currently report clearing transactions to CFTC-registered swap data repositories, thus evidencing their ability to report clearing transactions.[112] The Commission's determination to assign to registered clearing agencies the duty to report clearing transactions should promote efficiency in the reporting process under Regulation SBSR by leveraging these existing workflows.

In the Regulation SBSR Proposed Amendments Release, the Commission considered three alternatives to requiring the clearing agency to report clearing transactions: (1) Utilize the reporting hierarchy in existing Rule 901(a)(2)(ii); (2) modify that reporting hierarchy to place registered clearing agencies above other non-registered persons, but below registered security-based swap dealers and major security-based swap participants; and (3) require the reporting side of the alpha to report both the beta and the gamma.[113] The Commission assessed each alternative and expressed the preliminary view that none would be as efficient and reliable as assigning the reporting duty to the registered clearing agency.[114] The Commission noted that each of the three alternatives could place the duty to report the clearing transaction on a person who does not have information about the clearing transaction at the time of its creation; to discharge its duty, this person would have to obtain necessary transaction information from the registered clearing agency or from a counterparty to the registered clearing agency.[115]

One commenter urged the Commission to adopt Alternative 3—*i.e.,* to designate the reporting side for the alpha as the reporting side for the beta and gamma.[116] The commenter stated that the non-clearing-agency counterparties to the beta and gamma will always obtain information regarding their clearing transactions as a part of the clearing process.[117] The commenter suggested, therefore, that Alternative 3 would not result in unnecessary data transfers prior to reporting. In support of Alternative 3, the commenter noted that an alpha counterparty could rely on a "middleware reporting agent [who] could perform all steps necessary to report an alpha transaction as well as the associated beta and gamma security-based swaps in a matter of seconds, while a clearing agency could, at best, perform only the last two steps."[118] Furthermore, while endorsing Alternative 3, the commenter also believed that Alternatives 1 and 2 would be preferable to the Commission's proposed approach.[119]

Finally, the commenter suggested a fourth alternative to address the concern of an alpha counterparty having to report a clearing transaction to which it is not a counterparty. The commenter suggested that "the platform would remain the reporting side for all platform-executed trades while for bilateral or off platform cleared transactions, the reporting side would be the clearing agency. However, the clearing agency would be required to submit beta and gamma trade records to the alpha SDR (which would be determined by the alpha trade reporting side and not the clearing agency)."[120]

The Commission believes that assigning reporting duties for clearing transactions to registered clearing agencies will be more efficient and reliable than any of the alternatives discussed in the Regulation SBSR Proposed Amendments Release or

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about beta and gamma security-based swaps and that the reporting hierarchy in Rule 901(a)(2)(ii) is not suitable for reporting clearing transactions).

[105] Better Markets Letter at 4.

[106] *Id.* at 2.

[107] *See* ICE Letter at 5; LCH.Clearnet Letter at 8.

[108] ISDA/SIFMA Letter at 24.

[109] *See* Markit Letter at 2–3.

[110] *See* DTCC Letter at 5–6.

[111] In its capacity as a reporting side, a registered clearing agency must report all of the primary trade information and secondary trade information required by existing Rules 901(c) and 901(d), respectively, for each security-based swap to which it is a counterparty. *See infra* Section III(F) (discussing the UICs that a registered clearing agency must report).

[112] *See* ICE Letter at 5; LCH.Clearnet Letter at 8. The Commission notes that the CFTC has adopted rules that would impose reporting responsibilities on these clearing agencies similar to those that the Commission is adopting today. *See* Amendments to Swap Data Recordkeeping and Reporting Requirements for Cleared Swaps, Final Rule, 80 FR 41736 (June 27, 2016).

[113] *See* 80 FR at 14745–46.

[114] *See id.*

[115] *See id.,* 80 FR at 14746.

[116] *See* Markit Letter at 13.

[117] *See id.* at 5, 13. The commenter stated that a clearing agency "must, as a matter of course, send the cleared SBS trade record straight through to the sides of the trade or, if relevant, any non-affiliated reporting side (*e.g.,* the platform or reporting agent). In other words, for the clearing agency to transmit a message indicating that a trade has or has not been accepted for clearing (a necessary last step to conclude cleared transactions between the clearinghouse and the parties to the beta and gamma trades) there is no 'extra step.'" *Id.* at 5.

[118] *Id.* at 7 (also stating that the interconnectedness of the middleware provider makes it "better able to ensure the accuracy of trade records and the linkage between alpha, beta, and gamma trade records").

[119] *See id.* at 13 ("these other alternatives, relative to the Proposal, encourage competition based on quality of service and cost and the rule of reporting agents and are more likely to result in outcomes whereby the same SDR will receive alpha, beta, and gamma trades").

[120] *Id.*

raised by the commenter. Because each of these alternatives could assign the reporting duty to a person who does not have information about the clearing transaction at the time of its creation, the person with the reporting duty would have to rely on the clearing agency, directly or indirectly, to provide it with the information to be reported:

- Alternative 1 would be to utilize the existing reporting hierarchy in Regulation SBSR. Since a registered clearing agency is not a registered security-based swap dealer or registered major security-based swap participant, it would occupy the lowest rung in the hierarchy. Therefore, in any clearing transaction between a registered clearing agency and a registered security-based swap dealer or registered major security-based swap participant, the registered security-based swap dealer or registered major security-based swap participant would incur the reporting duty. However, the registered security-based swap dealer or registered major security-based swap participant would be dependent on the registered clearing agency to supply the information that must be reported.[121]
- Alternative 2 is similar to Alternative 1 in that the registered security-based swap dealer or registered major security-based swap participant with the reporting duty would be dependent on the registered clearing agency to supply the information that would be reported.
- Alternative 3 would designate the reporting side for the alpha as the reporting side for the beta and gamma. Under this alternative, the alpha reporting side would need to obtain information from the clearing agency to report its own clearing transaction. The alpha reporting side also would need to obtain, either from the non-reporting side or from the registered clearing agency, information about the clearing transaction of the alpha's non-reporting side. The Commission believes that Alternative 3 would be difficult to implement operationally and could create confidentiality concerns, because it does not offer a mechanism for reporting of subsequent clearing positions created by the registered clearing agency in the account of the non-reporting side of the alpha.[122]
- Under the fourth alternative,[123] while the Commission concurs with the approach of requiring the registered clearing agency to report the resulting beta and gamma transactions, the Commission believes that the registered clearing agency, when it has the duty to report security-based swaps, should be able to choose the registered SDR to which it reports.[124]

In general, the Commission believes that Regulation SBSR should not assign reporting obligations to persons who lack direct access to the information necessary to make the report. With respect to clearing transactions, a person who lacked direct access to the necessary information would be obligated to obtain the information from the clearing agency or another party who has access to that information to discharge its reporting duties. Placing the reporting duty on the non-clearing-agency side would create additional reporting steps and each extra reporting step could introduce some possibility for discrepancy, error, or delay. The Commission believes that discrepancies, errors, and delays are less likely to occur if the duty to report clearing transactions is assigned to registered clearing agencies directly, because there would be no intermediate steps where data would have to be transferred between parties before it is sent to a registered SDR. Therefore, the Commission is adopting Rule 901(a)(2)(i) as proposed. A registered clearing agency has complete information about all clearing transactions to which it is a counterparty. This includes not only betas and gammas that arise from clearing alphas, but also security-based swaps that result from the clearing agency netting together betas and gammas of the same person in the same product to create new open positions in successive netting cycles. Under the alternatives discussed above, a person other than the registered clearing agency would have to obtain information from the clearing agency to report the clearing transactions—not just once, to report the initial beta and gamma, but potentially with every netting cycle of the registered clearing agency. This further increases the risks that there could be discrepancies, errors, or delays in reporting new clearing transactions as they are created.

The commenter who endorsed Alternative 3 also argued that "[t]he Proposal's failure to acknowledge the efficiency benefits and reduced costs that result from the presence of middleware reporting agents is a serious defect." [125] To the contrary, the Commission has considered the potential economic effects of new Rule 901(a)(2)(i) and the alternatives noted above, including the role that agents might play in reporting security-based swap transactions under these different alternatives.[126] The Commission notes that, while Regulation SBSR permits the use of agents to carry out reporting duties, it does not require the use of an agent.

C. Choice of Registered SDR for Clearing Transactions

In the Regulation SBSR Proposed Amendments Release, the Commission considered whether, if a registered clearing agency is assigned the duty to report clearing transactions, the clearing agency should be permitted to choose the registered SDR to which it reports or whether it should be required to report them to the alpha SDR.[127] The Commission proposed to allow a registered clearing agency to choose the registered SDR to which it reports clearing transactions.[128] The Commission recognized that this approach might result in beta and gamma security-based swaps being reported to a registered SDR other than the alpha SDR, thereby requiring the Commission to link these trades together across SDRs.[129]

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[121] For any clearing transaction between a registered clearing agency and a non-registered person that is not guaranteed by a registered security-based swap dealer or registered major security-based swap participant, the reporting hierarchy in existing Rule 901(a)(2)(i) would require the sides to select the reporting side. In these circumstances, it is likely that the counterparties would select the registered clearing agency as the reporting side for the clearing transactions. Assigning the duty to report clearing transactions directly to the clearing agency is consistent with the Commission's objective of minimizing the possibility that the reporting obligation would be imposed on a non-registered counterparty. *See* Regulation SBSR Adopting Release, 80 FR at 14598.

[122] Assume, under Alternative 3, that P and Q execute a security-based swap (S1) and submit it to a registered clearing agency (CA). P is the reporting side of the S1 alpha. When CA accepts the alpha for clearing, P would then have to report the beta between P and CA and the gamma between Q and CA (gamma1). Further assume that Q executes a second transaction (S2) in the same product as S1 with R, and that R is the reporting side for S2. If CA accepts S2 for clearing, R then must report the beta between R and CA and the gamma between Q and CA (gamma2). In its next netting cycle, CA nets together gamma1 and gamma2 to create a new security-based swap representing the net open position (NOP) of Q in that product. Under Alternative 3, it is unclear who should report NOP as between P and R, because NOP is a security-based swap resulting from the netting of security-based swaps involving both P and R. Furthermore, Q likely will not want P or R to know of its additional activity in that product with other counterparties.

[123] *See* Markit Letter at 13.

[124] *See infra* Section III(C).

[125] Markit Letter at 8. *See also id.* at 6 ("The Proposal ignores the efficiency gains resulting from the presence of middleware reporting agents in the market for SDR and post-trade processing services despite noting such benefits in the Regulation SBSR Final Rule") and 8 ("The efficiency benefits introduced by the presence of middleware reporting agents, if they were properly accounted for by the Commission . . . would have provided additional and, in our opinion, decisive support to the three alternative approaches described by the Commission").

[126] *See infra* Sections XIII(A) and (B).

[127] *See* 80 FR at 14746–47.

[128] *See id.*

Some commenters supported the Commission's proposal to allow the registered clearing agency to select the registered SDR to which it reports.[130] Other commenters, however, recommended that the Commission require the registered clearing agency to report the beta and gamma transactions to the alpha SDR.[131] These commenters generally believed that requiring beta and gamma security-based swaps to be reported to the alpha SDR would reduce data fragmentation and enhance the Commission's ability to obtain a complete and accurate understanding of the security-based swap market.[132]

One commenter endorsed the view that clearing should be considered a life cycle event of the alpha transaction, and that the clearing agency should be required to report the termination of the alpha, as well as the beta and gamma, to the alpha SDR.[133] In this commenter's view, "[m]aintaining all records related to an alpha trade in a single SB SDR will help to ensure that regulators are able to efficiently access and analyze all reports related to an SB swap regardless of where or how the transaction was executed and whether it is cleared." [134]

Another commenter noted that, in its experience with CFTC swap data reporting rules, clearing agencies "generally send beta and gamma records to an affiliated SDR" even though other market participants generally prefer using an SDR not affiliated with the clearing agency.[135] In this commenter's view, clearing agencies do not "provide services or fees that make them competitive as SDRs for all swap trade records." [136] The commenter believed that the Commission's proposed approach would result in tying of clearing services to SDR services and create a market for SDR and post-trade processing services that is unresponsive to market forces.[137] The commenter also stated that "middleware reporting agents can offer an even lower price" than registered clearing agencies for reporting beta and gamma transactions.[138]

Regulation SBSR generally allows the person with a duty to report to choose the registered SDR to which it reports.[139] This approach is designed to promote efficiency by allowing the person with the reporting duty to select the registered SDR based on greatest ease of use, the lowest fees, or other factors that are relevant to the person with whom the duty rests. As noted in the Regulation SBSR Adopting Release, a clearing transaction is an independent security-based swap and not a life cycle event of an alpha security-based swap that is submitted to clearing.[140] Under Rule 901(a)(2)(i), as adopted herein, a registered clearing agency is the reporting side for all clearing transactions to which it is a counterparty; because the registered clearing agency has the duty to report, it also has the ability to choose the registered SDR. The Commission considered requiring the registered clearing agency to report the beta and gamma to the alpha SDR. But had the Commission done so, the registered clearing agency would be required to report clearing transactions to a registered SDR that might not offer the clearing agency what it believes to be the most efficient or convenient means of discharging its reporting duty, as others with a reporting duty are permitted to do. As noted in Section XIII(A), *infra*, a clearing agency may be able to realize efficiency gains through vertical integration of clearing and SDR services and may choose to use an affiliated SDR. However, if an independent SDR or middleware reporting agent offers a competitive service model that provides a clearing agency with a duty to report a more efficient or cost-effective means of fulfilling its reporting obligations, the registered clearing agency may choose to use those instead.

One commenter expressed the view that requiring the beta and gamma to be reported to the alpha SDR would help to ensure that regulators are able to efficiently access and analyze all reports related to a security-based swap.[141] The commenter also stated that a clearing agency will need to incur costs to establish connections with alpha SDRs for purposes of reporting whether or not the clearing agency has accepted the alpha for clearing.[142] The commenter cautioned, furthermore, that "[t]he proposed process assumes that, in all instances, the transaction ID provided to the clearing agency would be accurate." [143] The commenter stated that only the alpha SDR would be able to ascertain whether the alpha transaction ID is valid based on its existing inventory.[144] The commenter concluded that, "[r]ather than establishing a complex reporting process for clearing transactions and potentially introducing data quality issues . . . the Commission [should] consider preservation of high quality data and ready access to a full audit trail as the paramount concerns that should govern the choice of SB SDR for clearing transactions." [145] Finally, the commenter questioned the ease with which the Commission would be able to track related transactions across SDRs through the transaction ID, stating that "the Commission would likely be forced to expend significant resources harmonizing data sets from multiple SDRs, thereby hindering the Commission's ready access to a comprehensive audit trail." [146]

The Commission has considered the commenter's arguments but continues to believe that it is appropriate to allow a registered clearing agency to choose the registered SDR to which it reports. Although the commenter is correct that Regulation SBSR will require a registered clearing agency to report to the alpha SDR whether or not the clearing agency accepts the alpha for clearing, this does not necessarily mean that the clearing agency would find it more efficient or convenient to make initial (and life cycle event) reports of clearing transactions to the alpha SDR. Betas, gammas, and transactions that arise from subsequent clearing cycles are independent security-based swaps. It is possible that a registered clearing agency might conclude that a registered SDR other than the alpha SDR is better suited for reporting these new transactions. Of course, if the registered clearing agency determines that reporting beta and gamma security-based swaps to the alpha SDR is, in fact, equally convenient or more convenient than connecting and reporting to a different SDR, the registered clearing agency would be free to make this choice under new Rule 901(a)(2)(i).

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[129] *See id.*

[130] *See* ICE Letter at 1; LCH.Clearnet Letter at 3; ISDA/SIFMA Letter at 24.

[131] *See* Better Markets Letter at 2, 4–5 ("we are concerned that allowing the clearing agency to report data to a different SDR than the one to which the initial alpha trade was reported could cause potential complications, such as double-counting or bifurcated data"); DTCC Letter at 2, 6; Markit Letter at 6.

[132] *See id. See also* DTCC Letter at 5 (predicting that the Commission "would encounter various implementation challenges" in linking alpha security-based swaps to the associated beta and gamma transactions that had been reported to different SDRs because SDRs might "store, maintain, and furnish data to regulators in formats different from other trade repositories").

[133] *See* DTCC Letter at 4, 6.

[134] DTCC Letter at 4.

[135] Markit Letter at 6.

[136] *Id.*

[137] *See id.* at 2–3, 12 (stating that, if a registered clearing agency is permitted to choose the registered SDR to which it reports clearing transactions, the clearing agency "can more easily leverage a dominant clearing agency position to gain a dominant SDR positon by selecting an affiliated SDR as its SDR of choice for beta and gamma trades").

[138] *See id.* at 4, 7–8 (noting that, "[i]n contrast to currently registered SBS clearing agencies . . . middleware reporting agents, such as MarkitSERV, are connected to numerous trade repositories globally and have achieved economies of scale with respect to the straight-through processing of cleared swaps across numerous clearinghouses and regulatory reporting regimes").

[139] *See* Regulation SBSR Adopting Release, 80 FR at 14597–98 ("The reporting side may select the registered SDR to which it makes the required report").

[140] *See* 80 FR at 14599, n. 291. However, the determination by a registered clearing agency of whether or not to accept the alpha for clearing is a life cycle event of the alpha transaction. As discussed above, new Rule 901(e)(1)(ii) requires a registered clearing agency to report these life cycle events to the alpha SDR.

[141] *See* DTCC Letter at 4. *See also* Markit Letter at 13 (raising as an alternative to the Commission's proposed approach that the Commission should require a clearing agency to report the beta and gamma to the alpha SDR).

[142] *See* DTCC Letter at 5.

[143] *Id.* The commenter added that it has encountered issues under the CFTC's swap reporting framework when transaction IDs have been reported inconsistently for the same trade. *See id.*

[144] *See id.*

[145] *Id.*

[146] *Id.*

The Commission shares the commenter's concern about ensuring that a termination reported by a registered clearing agency to an alpha SDR includes a valid transaction ID of an alpha held by that SDR and acknowledges the commenter's observation that this might not always occur in the CFTC's swap reporting regime. Because Rule 901(g) requires a registered SDR to assign a transaction ID to each security-based swap (or establish or endorse a methodology for transaction IDs to be assigned by third parties), the registered SDR should know the transaction ID of every security-based swap reported to it on a mandatory basis. If a registered clearing agency submits a termination report with a transaction ID that the registered SDR cannot match to an alpha transaction report, the registered SDR's policies and procedures must specify how this situation will be addressed.[147] The SDR's policies and procedures could provide, for example, that the registered SDR will hold the termination report from the registered clearing agency in a pending state until either (1) the registered SDR obtains a valid transaction ID from the registered clearing agency (if the registered clearing agency originally had reported an incorrect transaction ID); or (2) the registered SDR determines that it can otherwise match the termination report against the correct alpha (if the clearing agency reported the correct transaction ID but the correct transaction ID did not for some reason appear in the report of the alpha transaction). Furthermore, in the Regulation SBSR Proposed Amendments Release, the Commission acknowledged that it might not be possible for a registered SDR to determine immediately whether a particular transaction ID is invalid because a registered clearing agency could report whether or not it has accepted an alpha for clearing before the registered SDR has received a transaction report for that alpha.[148] The Commission stated that, in such case, the registered SDR should address this possibility in its policies and procedures, which could provide, for example, that the registered SDR would hold a registered clearing agency's report of the disposition of an alpha in a pending state until the registered SDR receives the transaction report of the alpha; the registered SDR could then disseminate as a single report the security-based swap transaction information and the fact that the alpha had been terminated.[149] Because the reporting side for an alpha generally has 24 hours from the time of execution to report the transaction,[150] the duration of the pending state generally should not exceed 24 hours after receipt of the clearing agency's report of whether or not it has accepted the alpha for clearing. The Commission staff intends to evaluate whether the termination reports submitted by registered clearing agencies to an alpha SDR are appropriately matched to the alpha.

The Commission also believes that the adopted approach of allowing a registered clearing agency to choose the registered SDR to which it reports clearing transactions is, unlike any alternatives considered,[151] properly designed to account for the possibility that alphas could be reported to several different SDRs. Consider the following example:

- On Day 1, Party A executes three alpha transactions (T1, T2, and T3) in Product XYZ.
- T1 is reported to SDR1. T2 is reported to SDR2. T3 is reported to SDR3.
- All three alpha transactions are submitted to Clearing Agency K and accepted for clearing.
- Clearing Agency K creates Beta1 and Gamma1 after terminating T1, Beta2 and Gamma2 after terminating T2, and Beta3 and Gamma3 after terminating T3.
- Assume that Party A is the direct counterparty to Beta1, Beta2, and Beta3.

If, as suggested by some commenters, the Commission required Beta1 and Gamma1 to be reported to SDR1, Beta2 and Gamma2 to be reported to SDR2, and Beta3 and Gamma3 to be reported to SDR3, operational difficulties would result when Clearing Agency K nets Beta1, Beta2, and Beta3 as part of its settlement cycle because each of the Betas has been reported to a different SDR.

- At the end of Day 1, Clearing Agency K nets Beta1, Beta2, and Beta3 together to create a net open position (NOP) of Party A in Product XYZ.
- As part of the netting process, Clearing Agency K terminates Beta1, Beta2, and Beta 3. Under new Rule 901(e)(1)(ii), Clearing Agency K would have to report the termination of Beta1 to SDR1, the termination of Beta2 to SDR2, and the termination of Beta3 to SDR3.
- NOP is a new security-based swap and must be reported to a registered SDR.

Under the commenters' alternate approach, it is not apparent which registered SDR should receive the report of NOP, because NOP incorporates transactions that were originally reported to three different registered SDRs. Reporting NOP to each of SDR1, SDR2, and SDR3 serves no purpose because the same position would be reflected in three separate SDRs and could lead to confusion about the true size of the security-based swap market.

The Commission also disagrees with the commenter's view that the Commission's ability to understand or analyze reported data would be impaired by permitting registered clearing agencies to select the registered SDR for reporting clearing transactions.[152] The Commission acknowledges that it will likely be necessary for the Commission's staff to link an alpha to the associated beta and gamma across different SDRs to obtain a complete understanding of transactions that clear. The Commission believes, however, that there are sufficient tools to facilitate this effort. Existing Rule 901(d)(10), for example, requires reporting of the "prior transaction ID" if a security-based swap arises from the allocation, termination, novation, or assignment of one or more prior security-based swaps. Therefore, the Commission believes that it is appropriate to allow a registered clearing agency to choose where to report the beta and gamma, even if it chooses to report to a registered SDR other than the alpha SDR.

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[147] *See* Rule 13n–5(b)(1)(i) under the Exchange Act, 17 CFR 240.13n–5(b)(1)(i) (requiring every SDR to establish, maintain, and enforce written policies and procedures reasonably designed for the reporting of complete and accurate transaction data); Rule 13n–5(b)(1)(iii) under the Exchange Act, 17 CFR 240.13n–5(b)(1)(iii) (requiring every SDR to establish, maintain, and enforce written policies and procedures reasonably designed to satisfy itself that the transaction data that has been submitted to the SDR is complete and accurate).

[148] *See* Regulation SBSR Proposed Amendments Release, 80 FR at 14748.

[149] *See id.*

[150] *See* Rule 901(j).

[151] *See supra* notes 113 to 124 and accompanying text.

[152] *See* DTCC Letter at 4.

The Commission acknowledges that permitting a registered clearing agency to report clearing transactions to a registered SDR other than the alpha SDR also could increase complexity for market participants who would prefer to have reports of all of their security-based swaps in a single SDR.[153] The Commission notes that SDRs are required to "collect and maintain accurate SBS transaction data so that relevant authorities can access and analyze the data from secure, central locations, thereby putting them in a better position to monitor for potential market abuse and risks to financial stability." [154] The Commission notes, in addition, that Regulation SBSR permits a security-based swap counterparty to make non-mandatory reports of security-based swaps to an SDR of its choice (if the SDR is willing to accept them).[155] Thus, to the extent that SDRs are willing to accept such non-mandatory reports, non-clearing-agency counterparties of clearing transactions would have a mechanism for consolidating reports of their transactions in a single SDR if such counterparties wished to do so.

The Commission does not agree with the assertion made by one commenter that permitting a registered clearing agency to report clearing transactions to a registered SDR of its choice necessarily results in the tying of clearing services to SDR services.[156] Under the rules being adopted today, the user of clearing services—*i.e.,* an alpha counterparty that clears a security-based swap at a registered clearing agency—has no obligation to report the subsequent clearing transaction.

Because Regulation SBSR does not require an alpha counterparty to have ongoing obligations to report subsequent information about the clearing transaction, such as life cycle events or daily marks, to the registered SDR that is selected by the clearing agency, alpha counterparties will not be required to establish connections to multiple SDRs and to incur fees for reporting information to those SDRs.

D. Scope of Clearing Agencies Covered by Final Rules

Proposed Rule 901(a)(2)(ii) would assign clearing agencies a duty to report under Regulation SBSR based on their registration status, not on their principal place of business. Thus, a foreign clearing agency, like a U.S. clearing agency, would be required to report all security-based swaps of which it is a counterparty if it is registered with the Commission. Commenters had differing recommendations with respect to the scope of clearing agencies that should be covered by proposed Rule 901(a)(2)(ii). Two commenters expressed the view that the rule should apply to all registered clearing agencies, regardless of their principal place of business.[157] A third commenter agreed that a registered clearing agency with its principal place of business inside the United States should be required to report all clearing transactions, but took a different view with respect to a registered clearing agency with its principal place of business outside the United States; the non-U.S. clearing agency, according to the commenter, should be required to report only clearing transactions involving a U.S. person.[158]

Final Rule 901(a)(2)(i) assigns the reporting obligation for a clearing transaction to a *registered* clearing agency that is a counterparty to the transaction. The rule applies to any registered clearing agency without regard to the location of its principal place of business. The Commission generally believes that, if a person registers with the Commission as a clearing agency, it should assume the same obligations as all other persons that register as clearing agencies.[159] Conversely, new Rule 901(a)(2)(i) does not apply to unregistered clearing agencies (*e.g.,* persons that act as clearing agencies outside the United States that are not required to, and choose not to, register with the Commission).

A fourth commenter requested the Commission to clarify whether clearing agencies that are "deemed registered" under the Exchange Act are "registered clearing agencies" for purposes of Regulation SBSR, which would trigger the duty to report clearing transactions even before they complete a full registration process with the Commission.[160] The Commission previously has stated that each clearing agency that is deemed registered is required "to comply with all requirements of the Exchange Act and the rules and regulations thereunder applicable to Registered Clearing Agencies." [161] Pursuant to this guidance, a "deemed registered" clearing agency is required to comply with all requirements of Regulation SBSR that are applicable to registered clearing agencies.[162]

E. Reporting Under the Principal Model of Clearing

Two commenters acknowledged that the agency model of clearing predominates in the United States but requested that the Commission clarify the application of Rule 901(a)(2)(ii) to security-based swaps cleared under the principal model of clearing.[163] One of these commenters recommended that the Commission require all clearing transactions to be reported according to the workflows used in the agency model of clearing.[164] By contrast, the other

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[153] *See id.* at 16.

[154] SDR Adopting Release, 80 FR at 14440.

[155] *See* Rule 900(r) (defining a "non-mandatory report" as any information provided to a registered SDR by or on behalf of a counterparty other than as required by Regulation SBSR).

[156] *See* Markit Letter at 3, 9–10.

[157] *See* LCH.Clearnet Letter at 9 ("Registered clearing agencies are best placed to report cleared transactions. Assigning these obligations to other participants for foreign domiciled clearing agencies will needlessly complicate the reporting landscape"); ISDA/SIFMA Letter at 24.

[158] *See* ICE Letter at 5.

[159] The Commission notes, however, that the reporting duty of a registered clearing agency under new Rule 901(a)(2)(i) must be read in connection with Rule 908(a), amendments to which the Commission is adopting today. In other words, a registered clearing agency must report only those security-based swaps that fall within Rule 908(a). It is likely that many clearing transactions of a registered clearing agency having its principal place of business outside the United States would not fall within any prong of Rule 908(a) and thus would not have been reported by the registered clearing agency pursuant to Rule 901(a)(2)(i). For example, a clearing transaction between a registered clearing agency and a non-U.S. person that is not registered with the Commission as a security-based swap dealer or major security-based swap participant, and who is not utilizing U.S. personnel to arrange, negotiate, or execute the clearing transaction, would not fall within any prong of Rule 908(a).

[160] *See* ISDA/SIFMA at 26.

[161] Securities Exchange Act Release No. 69284 (April 3, 2013), 68 FR at 21046, 21048 (April 9, 2013).

[162] This commenter also sought guidance regarding the reporting obligations relating to a security-based swap between a clearing agency that has been exempted from registration by the Commission and a counterparty. *See* ISDA/SIFMA Letter at 26. The Commission does not believe that this issue is ripe for consideration. The Commission anticipates that it would consider this issue if it exempts from registration a clearing agency that acts as a central counterparty for security-based swaps.

[163] *See* ISDA/SIFMA Letter at 25 ("Although we do not have reason to believe the principal model will become prevalent in the U.S. market, it will be used in a percentage of SBS reportable under SBSR especially by non-U.S. parties registered as SBSDs or MSBSPs which may be the direct or indirect counterparty to a SBS. Providing additional guidance on the treatment of SBS cleared via the principal model would be useful to promote data accuracy and consistency"); ICE Letter at 2–3.

[164] *See* ICE Letter at 3 (arguing that reporting principal clearing workflows is unnecessarily complicated and costly and "results in a

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commenter argued that "a set of clearing transactions should be reported in accordance with the actual applied clearing model." [165]

The Commission concurs with the latter commenter: Regulation SBSR requires reporting of clearing transactions in accordance with the actual clearing model. Under the rules adopted today, any security-based swap that is a clearing transaction—*i.e.,* that has a registered clearing agency as a direct counterparty—must be reported by the registered clearing agency pursuant to new Rule 901(a)(2)(i).[166] If a security-based swap is not a clearing transaction, it must be reported by the person designated by the other provisions of Rule 901(a).

F. Clearing Transactions and Unique Identification Codes

Rules 901(c) and 901(d), respectively, require the person with the duty to report all of the primary trade information and secondary trade information for each security-based swap to which it is a counterparty. Noting that existing Rule 901(d)(2) requires the reporting side to report, as applicable, the branch ID, broker ID, execution agent ID, trader ID, and trading desk ID of the direct counterparty on the reporting side, the Commission in the Regulation SBSR Proposed Amendments Release asked whether these types of unique identification codes ("UICs") [167] would ever be applicable to a registered clearing agency when it incurs the duty to report a clearing transaction.[168] Three commenters suggested that these UICs are not applicable to clearing transactions and should not have to be reported by the clearing agency.[169]

The Commission agrees. In its capacity as a central counterparty for security-based swaps, a registered clearing agency does not engage in market-facing activity and thus would not utilize a branch, broker, execution agent, trader, or trading desk to effect security-based swap transactions. Therefore, these UICs are not applicable to clearing transactions, and a registered clearing agency need not report any UICs pursuant to Rule 901(d)(2).[170]

G. Reporting Whether an Alpha Transaction Is Accepted for Clearing

Existing Rule 901(e)(1)(i) addresses the reporting requirements for most life cycle events and assigns the reporting duty for reporting those life cycle events to the reporting side of the original transaction. However, Rule 901(e)(1)(i) specifically provides that "the reporting side shall not report whether or not a security-based swap has been accepted for clearing." In the Regulation SBSR Proposed Amendments Release, the Commission proposed a new paragraph (ii) to Rule 901(e)(1) that would require a registered clearing agency that receives an alpha to report to the alpha SDR whether or not it has accepted the alpha for clearing.[171]

Two commenters expressed support for proposed Rule 901(e)(1)(ii), noting that clearing agencies would be well-positioned to issue a termination report for the alpha and subsequently to report the beta and gamma to a registered SDR.[172] However, two commenters objected to proposed Rule 901(e)(1)(ii). One of these commenters argued that proposed Rule 901(e)(1)(ii) was unnecessary because the counterparties to the alpha would learn of the disposition of the alpha from the clearing agency in the normal course of business, and could report this information to the alpha SDR.[173] This commenter further asserted that concerns regarding "data discrepancies, errors, or delays" cited by the Commission in support of proposed Rule 901(e)(1)(ii) were unfounded and could be addressed, if necessary, through rulemaking or enforcement action to encourage clearing agencies to provide accurate and timely data to platforms and counterparties about clearing dispositions.[174] Similarly, the second commenter that objected to proposed Rule 901(e)(1)(ii) argued that the "party that originally reported the alpha trade is best placed to report the result of clearing" [175] and that clearing agencies should not have to incur costs associated with establishing connectivity to alpha SDRs.[176] This commenter also questioned why the Commission's approach to the reporting of cleared transactions differed from its approach to the reporting of prime brokerage transactions,[177] where the Commission is requiring that the person who reported the initial leg of a prime brokerage transaction (not the prime broker) must report any life cycle event

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duplicative representation of cleared records submitted to repositories").

[165] ISDA/SIFMA Letter at 26.

[166] Existing Rule 902(c)(6) provides that a registered SDR shall not disseminate any information regarding a clearing transaction that arises from the acceptance of a security-based swap for clearing by a registered clearing agency or that results from netting other clearing transactions.

[167] *See* Rule 900(qq) (defining "UIC" as "a unique identification code assigned to a person, unit of a person, product, or transaction").

[168] *See* 80 FR at 14752.

[169] *See* DTCC Letter at 16; ICE Letter at 4; LCH.Clearnet Letter at 8.

[170] The Commission also deems these UICs "not applicable" to the non-clearing agency side of a clearing transaction; therefore, under Rule 906(a), a registered SDR need not query a non-clearing-agency participant for these UICs with respect to a clearing transaction, and the participant need not provide these UICs to the registered SDR with respect to any clearing transaction. As the Commission has previously stated when exempting most types of clearing transactions from public dissemination, clearing transactions "are mechanical steps taken pursuant to the rules of the clearing agency." Regulation SBSR Adopting Release, 80 FR at 14610. *See also* Rule 902(c)(6). Thus, the Commission does not believe that clearing transactions can meaningfully be said to involve a market-facing subdivision or agent of the counterparty such as the branch, trading desk, individual trader, broker, or execution agent. To the extent that there was meaningful participation by a branch, trading desk, individual trader, broker, or execution agent on behalf of the counterparty, these UICs must be provided in connection with the original alpha transaction—either in its capacity as the reporting side (in which case it would be required to provide these UICs pursuant to Rule 901(d)(2)) or as the non-reporting side (in which case it would be required to provide these UICs pursuant to Rule 906(a) if it were a participant of the registered SDR). *Cf.* DTCC Letter at 16 (while not specifically addressing the question of whether these UICs should be reported for the non-clearing-agency side of a clearing transaction, questioning whether the non-reporting side should be required to report these UICs for any transaction).

[171] *See infra* Section III(J) (discussing when an alpha has been rejected from clearing).

[172] *See* ICE Letter at 5 ("Upon acceptance for clearing, CAs should be required to report the alpha termination to the appropriate SDR storing the alpha swap"); ISDA/SIFMA Letter at 24 (noting that the proposal would prevent the "orphaning of alphas" that currently occurs under the CFTC swap data reporting rules). *Cf.* DTCC Letter at 5–6, 17 (expressing support for proposed Rule 901(e)(1)(ii), but in the context of DTCC's view, discussed *supra,* that clearing agencies also should be required to report betas and gammas to the alpha SDR).

[173] *See* Markit Letter at 5 ("the clearing agency must, as a matter of course, send the cleared SBS trade record straight through to the sides to the trade or, if relevant, any non-affiliated reporting side (*e.g.,* the platform or reporting agent). In other words, for the clearing agency to transmit a message indicating that a trade has or has not been accepted for clearing (a necessary last step to conclude cleared transactions between the clearinghouse and the parties to the beta and gamma trades), there is no 'extra step.' Moreover, the processing of cleared trades is nearly instantaneous, resulting in no operationally significant delay").

[174] *See id.* This commenter also argued that Rule 901(e)(1)(ii) would be unnecessary if the Commission permitted the reporting side of the alpha to select the SDR that will receive reports of the associated beta and gamma. *See id.* at 15.

[175] LCH.Clearnet Letter at 8.

[176] *See id.* at 8–10 (arguing that the incremental costs of assigning the reporting obligation to the alpha reporting side would be small compared to the costs associated with registered clearing agencies having to establish connectivity to alpha SDRs). The Commission notes that one of the commenters that supported the general approach of requiring registered clearing agencies to incur reporting duties argued also that "CAs [*i.e.,* clearing agencies] should not incur SDR fees to report alpha termination messages. Requiring CAs to become a full 'participant' of alpha SDRs, is unnecessary and overly burdensome for CAs." ICE Letter at 6.

[177] *See* LCH.Clearnet Letter at 7.

resulting from whether the prime broker accepts or rejects that transaction.[178]

After carefully considering the comments received, the Commission is adopting paragraph (ii) of Rule 901(e)(1) as proposed. Final Rule 901(e)(1)(ii) is consistent with the Commission's general approach of assigning the reporting obligation for a security-based swap transaction to the person with the most complete and efficient access to the required information at the point of creation. Because a registered clearing agency determines whether to accept an alpha for clearing and controls the precise moment when the transaction is cleared, the Commission believes that the clearing agency is best placed to report the result of its decision.

One commenter argued that requiring a registered clearing agency to report to an SDR not of its choosing whether it accepts an alpha for clearing "is in contradiction with the Commission's reasons for permitting a registered clearing agency to decide which registered SDR to use for reporting of beta and gamma trades."[179] The Commission does not believe that there is a contradiction in its reasoning. The person with the duty to report whether or not the alpha was accepted for clearing must report that information to the alpha SDR or else it would be difficult to pair the alpha transaction report with the report of its clearing disposition.[180] The Commission believes that a registered clearing agency, because it chooses when and how to handle an alpha that is submitted for clearing, is best placed to report whether or not it accepts the alpha for clearing.

The Commission considered, but determined not to adopt, the alternative recommended by certain commenters of assigning to the person who has the duty to report the initial alpha (and thus can choose the alpha SDR) the duty of also reporting to the alpha SDR whether or not the registered clearing agency has accepted the alpha for clearing. The Commission acknowledges, as one commenter pointed out, that counterparties to security-based swaps that are submitted to clearing would in the normal course learn from the clearing agency whether or not a security-based swap has been accepted for clearing. The Commission believes, however, that requiring a registered clearing agency to report the termination of the alpha will increase the likelihood that the alpha termination will be reported accurately and without delay, thereby helping to minimize the problem of orphan alphas and helping to promote the integrity of reported security-based swap information. The adopted approach centralizes the function of reporting alpha dispositions in self-regulatory organizations that operate under rules approved by the Commission. Centralizing this reporting function into registered clearing agencies, rather than relying on a potentially large number of platforms and reporting sides to report alpha clearing dispositions, should help minimize the potential for data discrepancies and delays.[181] Not all counterparties that may have a reporting obligation would be registered entities. The Commission thus has greater confidence in the ability of clearing agencies registered with the Commission to accurately report alpha dispositions. The Commission believes that the approach adopted today is preferable to an approach that would require platforms and reporting sides to report the alpha clearing disposition, given that these entities would first have to receive that information from the registered clearing agency. The Commission believes that the approach of requiring the registered clearing agency to report that information directly to the alpha SDR is preferable to relying on Commission rulemaking or enforcement action, as one commenter suggests,[182] to address data accuracy concerns arising from the exchange of information from the clearing agency to the platform or reporting side.

The Commission believes that the approach suggested by commenters to require the person who had the duty to report the alpha transaction also to report whether or not a clearing agency accepts an alpha for clearing is particularly unsuitable for situations where the alpha was executed on a platform and the platform incurs the duty to report that alpha under new Rule 901(a)(1).[183] A platform is not a counterparty to the transaction and thus, unlike a counterparty, typically would not monitor or record life cycle events, or be involved in post-trade processing, of any transactions executed on the platform (beyond sending messages about executed transactions to other infrastructures, such as SDRs and clearing agencies, that do carry out post-trade processing functions). The commenters' suggested approach of requiring the person who has the duty to report the alpha also to report whether or not the clearing agency has accepted the alpha for clearing would thus require platforms to develop processes for tracking and reporting life cycle events of platform-executed alphas that they currently do not have.

The Commission believes that it is more efficient to require a registered clearing agency to report all alpha dispositions, rather than having one rule for reporting the disposition of alphas that are executed on-platform and a different rule for reporting the disposition of alphas that are executed off-platform. The potential candidates for reporting the disposition of on-platform alphas include the platform, one of the sides of the alpha, and the clearing agency. As noted above, a platform is not well-positioned to perform this function. Furthermore, because neither side has the duty to report an on-platform alpha (because the platform has the duty), difficulty could arise from attempting to assign to one of the sides the duty to report the alpha disposition, particularly if the sides traded anonymously on the platform. Given the alternatives and for the reasons noted above, the Commission believes that the clearing agency is in the best position to report whether or not it has accepted a transaction for clearing, with respect to both on- and off-platform alphas. In this regard, the Commission notes that, once a clearing agency has established a mechanism for reporting to an SDR whether or not it has accepted on-platform alphas for clearing, there would be only minimal incremental burdens to send additional messages to that SDR to report whether or not the clearing agency has accepted off-platform alphas for clearing.

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[178] *See infra* Section VII (discussing application of Regulation SBSR to security-based swaps arising from prime brokerage arrangements).

[179] LCH.Clearnet Letter at 3.

[180] Existing Rule 901(e)(2) requires a life cycle event to be reported to the same entity to which the original security-based swap transaction was reported. A termination of an alpha resulting from action by a registered clearing agency is a life cycle event of the alpha, and thus must be reported to the alpha SDR. Requiring the clearing disposition report to go to the alpha SDR will allow the alpha SDR to match the relevant reports and understand the disposition of the alpha. Allowing the registered clearing agency to report the disposition of the alpha to a registered SDR of its choice, rather than to the alpha SDR, could make it difficult, if not impossible, to match the alpha transaction report with the report of the alpha's clearing disposition. The Commission seeks to minimize the problem of "orphan alphas," where it cannot readily be ascertained whether a transaction involving a product that is customarily submitted to clearing has in fact been submitted to clearing and, if so, whether it was accepted for clearing. If alpha transactions are not reported as terminated or they are reported as terminated but the alpha SDR cannot match the report of termination with the original transaction report—*i.e.*, the alpha is "orphaned"—it would be more difficult for the Commission to carry out various oversight functions, such as calculating the total amount of open exposures resulting from security-based swap activity and understanding trends in clearing activity, including adherence to any clearing mandate.

[181] The Commission estimates that four registered clearing agencies will clear security-based swaps and thus incur duties under Regulation SBSR. *See infra* Section XI(B)(2)(b)(ii).

[182] *See* Markit Letter at 5.

[183] *See infra* Section IV(A) (discussing adopting of new Rule 901(a)(1)).

As noted above, one commenter questioned why the Commission's approach to the reporting of whether or not an alpha is accepted for clearing differs from its approach to the reporting of life cycle events stemming from the acceptance or rejection by a prime broker of the initial leg of a prime brokerage transaction.[184] The commenter correctly understands that, in the prime brokerage context, the reporting side of the first transaction of a prime brokerage workflow (whether in a two- or three-legged scenario) must report the termination of that transaction.[185] In contrast, for a transaction submitted to clearing, the registered clearing agency, rather than the reporting side for the initial alpha transaction, must report whether or not it has accepted the alpha for clearing. The commenter disagrees with this approach to the reporting of transactions submitted to clearing, asserting that the reporting side or platform, as applicable, should report whether the alpha has been accepted for clearing.[186]

Although prime brokerage and clearing arrangements are similar in some ways, there also are differences that, the Commission believes, warrant different approaches to the reporting of a termination of the first leg of the overall transaction. A prime broker, like a registered clearing agency, has the most direct access to information about whether a transaction has been accepted. However, because a prime broker might not be subject to Rule 908(b) and thus might not be eligible to incur any duties under Regulation SBSR, there could be uncertainty as to who would be required to report the disposition of the first transaction. By contrast, a clearing transaction by definition includes a registered entity: The registered clearing agency. Therefore, there is no uncertainty as to whether the registered clearing agency could have the duty to report the disposition of the alpha.

Finally, two commenters expressed concern about the costs associated with requiring registered clearing agencies to report whether or not they accept alphas for clearing.[187] One commenter stated, for example, that "[c]onnecting to all registered SDRs is necessary to ensure that the registered clearing agency is prepared to report to any SDR to which an alpha trade could be reported . . . [T]here is a significant cost to establishing and maintaining connectivity to registered SDRs to facilitate the reporting required by Rule 901." [188] The second commenter argued that "CAs [*i.e.*, clearing agencies] should execute an agreement with [the alpha SDR] outlining the requirements to report termination messages; however, CAs should not incur SDR fees to report alpha termination messages." [189] This commenter cautioned, furthermore, that "[r]equiring CAs to become a full 'participant' of alpha SDRs is unnecessary and overly burdensome for CAs." [190]

With respect to whether a registered SDR may impose a fee on a registered clearing agency for reporting to the SDR whether or not an alpha transaction has been accepted for clearing, neither the statute nor the applicable rules prohibit such a fee. The Commission notes, however, that existing Rule 13n–4(c)(1)(i) under the Exchange Act[191] requires an SDR to ensure that any dues, fees, or other charges imposed by the SDR are fair and reasonable and not unreasonably discriminatory.

With respect to the wider costs associated with clearing agencies' reporting of alpha clearing dispositions to registered SDRs, the Commission notes that Rule 901(e)(1)(ii), by its terms, requires registered clearing agencies to report only a limited amount of information (*i.e.*, whether or not they have accepted a security-based swap for clearing, along with the transaction ID of the relevant alpha) and therefore does not require the clearing agency to have connectivity sufficient to report all of the primary and secondary trade information of a security-based swap.[192] The Commission believes that registered SDRs should consider providing a minimally burdensome means for registered clearing agencies to report whether or not they accept an alpha for clearing.[193]

Accordingly, for similar reasons that the Commission is assigning to registered clearing agencies the duty to report all clearing transactions, the Commission also believes that it is appropriate to assign to the registered clearing agency—rather than to the person who had the initial duty to report the alpha (*i.e.*, a reporting side or a platform)—the duty to report to the alpha SDR whether or not the clearing agency has accepted the alpha for clearing.

H. A Registered Clearing Agency Must Know the Transaction ID of the Alpha and the Identity of the Alpha SDR

Existing Rule 901(e)(2) requires the person who has the duty to report a life cycle event to include in the report of the life cycle event the transaction ID of the original transaction. Under new Rule 901(e)(1)(ii), a registered clearing agency that accepts or rejects an alpha transaction from clearing incurs this duty. The transaction ID of the alpha transaction is information that the registered clearing agency might not have, because the registered clearing agency is not involved in the execution or reporting of the alpha. Therefore, the Commission proposed a new paragraph (a)(3) of Rule 901(a), which would require the person who has the duty to report the alpha security-based swap to provide the registered clearing agency with the transaction ID of the alpha and the identity of the alpha SDR.

One commenter "acknowledged the value" of the proposed rule and noted that in other jurisdictions the data flows to clearing agencies already include identification information for alpha transactions, so these data flows should be extensible to the security-based swap market.[194] By contrast, a second commenter expressed the view that the proposed rule "would add a layer of complexity to the reporting framework" and noted that the reporting person for the alpha might provide an inaccurate transaction ID to the registered clearing agency to which the trade is submitted.[195]

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[184] *See* LCH.Clearnet Letter at 7.

[185] *See infra* Section VII(B) for a discussion of how Regulation SBSR applies to prime brokerage transactions, including both a two-legged and three-legged model.

[186] *See* LCH.Clearnet Letter at 3, 7.

[187] *See* ICE Letter at 6 (stating that a clearing agency "should not incur SDR fees to report alpha termination messages"); LCH.Clearnet Letter at 8–10.

[188] LCH.Clearnet Letter at 3.

[189] ICE Letter at 6.

[190] *Id.*

[191] 17 CFR 240.13n–4(c)(1)(i).

[192] As described in more detail in Section XII(A), *infra*, the Commission has considered the costs of requiring registered clearing agencies to have the capability to report clearing dispositions to multiple alpha SDRs and the benefits associated with ensuring that the clearing disposition report is made by the person with immediate and direct access to the relevant information.

[193] For example, a registered SDR should consider how it will comply with Rule 13n–4(c)(1)(ii) under the Exchange Act, 17 CFR 240.13n–4(c)(1)(ii), which requires that the SDR permit market participants to access specific services offered by the SDR separately, and Rule 13n–4(c)(1)(iii) under the Exchange Act, 17 CFR 240.13n–4(c)(1)(iii), which requires the SDR to have objective criteria that would permit fair, open, and not unreasonably discriminatory access to services offered and data maintained by the SDR, when offering access to a registered clearing agency that seeks only to report whether or not it has accepted individual transactions for clearing.

[194] *See* ISDA/SIFMA Letter at 25.

After carefully considering the comments received, the Commission is adopting Rule 901(a)(3) as proposed. Although Rule 901(a)(3) adds an additional step to the reporting framework, the Commission believes that this additional step is necessary to facilitate the linking of related transactions. Under new Rule 901(e)(1)(ii), a registered clearing agency must report to the entity to which the original security-based swap was reported whether or not it accepts the alpha for clearing. For the alpha SDR to link the registered clearing agency's report of acceptance or rejection to the appropriate transaction, the registered clearing agency must be able to include the transaction ID of the alpha transaction in its report to the alpha SDR. The Commission further believes that the person having the duty to report the alpha is best situated to also report the transaction ID of the alpha and the identity of the alpha SDR to the registered clearing agency. While it is true, as the commenter asserts, that the person having the duty to report the alpha might provide an inaccurate transaction ID to the registered clearing agency, the same could be said about any reporting requirement imposed by Regulation SBSR. This situation should be addressed, at least in part, by Rule 13n–5(b)(1)(i) under the Exchange Act,[196] which requires every SDR to establish, maintain, and enforce written policies and procedures reasonably designed for the reporting of complete and accurate transaction data to the SDR.[197] Furthermore, the person with the duty to report the alpha is certain to know the transaction ID and the identity of the alpha (since it selected the SDR) and thus is well placed to provide this information to the registered clearing agency, which would allow the clearing agency to discharge its duty under new Rule 901(e)(1)(ii).

Two commenters sought guidance regarding the means by which persons with the duty to report the alpha transaction could provide the transaction ID of the alpha and the identity of the alpha SDR to the registered clearing agency.[198] One of these commenters stated that some platforms can provide the information required by Rule 901(a)(3) using third-party service providers, but cautioned that "platforms would be forced to undertake a significant development investment if required to perform that function itself and to build functionality that replaces existing solutions." [199] The commenter requested, therefore, that the Commission "make clear in its final rules that platforms have discretion to determine the most appropriate technological manner in which they comply [with Rule 901(a)(3)]." [200] The other commenter expressed the view that "the most efficient approach would be for clearing agencies to gather the choice of alpha SDR for an asset class or product once from all reporting sides and platforms, and retain and maintain as static data rather than requiring a notification on a transactional basis." [201]

Final Rule 901(a)(3) does not prescribe a specific means by which the person with the duty to report an alpha must inform the registered clearing agency of the alpha's transaction ID and the identity of the alpha SDR. There is no prohibition on utilizing existing infrastructure. Thus, market participants may determine the most efficient way of communicating this information. The Commission notes, however, that Rule 901(a)(3) applies on a transaction-by-transaction basis. Thus, while it might be possible for a registered clearing agency to obtain and store static data regarding a reporting person's SDR preferences, Rule 901(a)(3) requires the person having the duty to report a particular alpha transaction to ensure that the registered clearing agency learns the identity of the SDR that holds the record of the *particular* alpha. If the person with the duty to report attempts to satisfy this obligation with static data and the data become stale or inaccurate with respect to a particular alpha, the reporting person would not satisfy its obligation under Rule 901(a)(3).

I. Alpha Submitted to Clearing Before It Is Reported to a Registered SDR

In the Regulation SBSR Adopting Release, the Commission described the interim phase for regulatory reporting and public dissemination,[202] under which security-based swap transactions may be reported up to 24 hours after the time of execution (or, if 24 hours after the time of execution would fall on a day that is not a business day, by the same time on the next day that is a business day).[203] However, the reporting timeframe for a life cycle event and any adjustment due to a life cycle event is within 24 hours after the occurrence of the life cycle event or the adjustment due to the life cycle event.[204] Thus, an alpha might be submitted for clearing immediately after execution but not reported until 24 hours later (or longer, if 24 hours after the time of execution would fall on a day that is not a business day), and the clearing agency's obligation under new Rule 901(e)(1)(ii) to inform the alpha SDR whether or not it has accepted the alpha for clearing could arise before the alpha SDR has received the alpha's initial transaction report.[205]

To account for this possibility, the Commission proposed to amend existing Rule 901(e)(2) to require a life cycle event (which would include a notification by a registered clearing agency whether or not it has accepted an alpha for clearing) to be reported "to the entity to which the original security-based swap transaction *will be reported or has been reported*" (emphasis added). This amendment mirrors the language in new Rule 901(a)(3), which requires a person who reports an alpha to provide the registered clearing agency the alpha's transaction ID and the identity of the registered SDR to which the alpha "will be reported or has been reported."

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[195] DTCC Letter at 4–5.

[196] 17 CFR 240.13n–5(b)(1)(i).

[197] A registered SDR should consider including in its policies and procedures under Rule 13n–5(b)(1)(i) what actions to take if it receives clearing disposition information from a registered clearing agency that includes transaction IDs of alpha transactions that do not match to the records of any alpha transactions held at the registered SDR. The SDR might seek to call this discrepancy to the attention of the registered clearing agency so that the registered clearing agency could work with persons who are required by Rule 901(a)(3) to provide the registered clearing agency with the transaction IDs of the alphas.

[198] *See* ISDA/SIFMA Letter at 25; WMBAA Letter at 3.

[199] WMBAA Letter at 3.

[200] *Id.*

[201] ISDA/SIFMA Letter at 25.

[202] *See* 80 FR at 14616–25.

[203] *See* Rule 901(j). In the case of a security-based swap that is subject to regulatory reporting and public dissemination solely by operation of Rule 908(a)(1)(ii) (*i.e.*, the security-based swap is accepted for clearing by a clearing agency having its principal place of business in the United States), Rule 901(j) requires reporting within 24 hours of the time of acceptance for clearing (or, if 24 hours after the time of acceptance would fall on a day that is not a business day, by the same time on the next day that is a business day).

[204] *See* Rule 901(j).

[205] To submit the report contemplated by new Rule 901(e)(1)(ii), the registered clearing agency must know the transaction ID of the alpha. The person with the duty to report the alpha might know the alpha's transaction ID before it reports the transaction to a registered SDR. Under existing Rules 903(a) and 907(a)(5) there is no requirement that a registered SDR itself assign a transaction ID. Under those rules, a registered SDR may allow third parties, such as reporting sides or platforms, to assign a transaction ID using a methodology endorsed by the registered SDR. If the registered SDR allows third parties to assign the transaction ID, the reporting side or platform could tell the registered clearing agency the alpha's transaction ID, which in turn could allow the registered clearing agency to report to the alpha SDR whether or not the alpha has been accepted for clearing before the alpha has been reported to the registered SDR. If, however, the person with the duty to report the alpha does not obtain the alpha's transaction ID until it reports the alpha to a registered SDR, the person could not provide the alpha's transaction ID to the registered clearing agency, and the registered clearing agency could not report whether or not it accepts the alpha for clearing until after it receives the alpha's transaction ID.

The Commission received two comments on this proposed amendment, discussed below.[206] For the reasons discussed below, the Commission is adopting the amendment to Rule 901(e)(2) as proposed.

One commenter stated that, "[i]n the situation where a termination message to an alpha swap is not found, the SDR should queue this message and attempt to reapply the termination message to newly submitted SBSs. This process should continue until the end of the current business day at which time an error message should be reported back to the clearing agency since the termination message could not be applied to a corresponding alpha." [207] The Commission notes that it is not requiring a registered SDR to use a particular workflow to account for circumstances where the report of a life cycle event precedes the initial transaction report. Under Rule 901(e)(2), each registered SDR may use the workflow that it finds most effective, provided that it satisfies the requirements of the rule. A registered SDR generally should consider whether the policies and procedures it establishes under Rule 907(a) will address the situation where it receives a report from a registered clearing agency stating whether or not it has accepted an alpha (with a particular transaction ID) for clearing before the registered SDR receives a transaction report of the alpha. The policies and procedures could provide, for example, that the registered SDR would hold in a pending state a report from a registered clearing agency that it accepted the alpha for clearing until the SDR receives the alpha transaction report, and then disseminate the security-based swap transaction information and the fact that the alpha has been terminated as a single report.

The second commenter argued that Regulation SBSR should "prohibit [the alpha SDR] from publicly disseminating the rejection or acceptance report from the clearing agency ahead of the point at which the SDR receives and has publicly disseminated the report for the alpha." [208] While the Commission shares the commenter's concern that a "stand alone" termination not be publicly disseminated without the associated transaction report, the Commission does not believe that a new rule is necessary to avoid this result. Under existing rules, a registered SDR that receives a termination report of a security-based swap before it receives the initial transaction report cannot disseminate anything relating to the transaction. Existing Rule 902(a) requires this result because it provides, in relevant part, that the public report "shall consist of all the information reported pursuant to [Rule 901(c)]." Because the registered SDR has not yet received the transaction report of the alpha, it would lack "all of the information reported" pursuant to Rule 901(c) and thus could not make the report required by Rule 902(a). If the registered SDR holds in queue the notice of the disposition of the alpha, it would be required—when it subsequently receives the initial alpha transaction report—to immediately disseminate the Rule 901(c) information pertaining to the alpha as well as the fact that the alpha has been terminated if the alpha has been accepted for clearing.[209]

J. Consequences of Rejection

Two commenters raised issues relating to the reporting of an alpha that is rejected from clearing.[210] One of these commenters stated that "[c]areful consideration needs to be made by SDRs as to how a report by the clearing agency that a trade has not been accepted for clearing would be reflected in the record for the SBS." [211] The other commenter noted that "[i]t is unclear what lifecycle event the registered clearing agency should report for rejected trades." [212] This commenter stated that an alpha that is rejected from clearing might remain a bilateral trade, might be submitted to a different registered clearing agency, might be re-submitted to the same registered clearing agency, or might be torn up.[213]

In some cases, depending on the contractual arrangement between the alpha counterparties, a registered clearing agency's rejection of an alpha will result in the immediate termination of the transaction.[214] In other cases, as the commenter indicates, an alpha that is rejected from clearing could remain a bilateral trade with different terms. The latter case implies that the counterparties had effected a bilateral, off-platform transaction and that their contractual arrangement specifically contemplated that the counterparties could elect to preserve the original security-based swap as a bilateral transaction if the clearing agency rejects it from clearing.[215] If the alpha counterparties do not have such an arrangement, then rejection from clearing terminates the alpha.[216] But if the counterparties have such an arrangement and elect to preserve a transaction that has been rejected from clearing, the reporting side of the original transaction would be required by Rule 901(e) to report the amended terms of the security-based swap to the registered SDR as a life cycle event of the original transaction.[217] A registered SDR must establish and maintain written policies and procedures for specifying procedures for reporting life cycle events, including those relating to a clearing agency's rejection of an alpha. A registered SDR could, for example, provide in its policies and procedures that it would, in the absence of any information provided by the reporting side to the contrary or in the case of a platform-executed alpha, treat the clearing agency's rejection of the alpha as a termination of the alpha.

As noted in Section III(I), *supra,* during the interim phase for regulatory reporting and public dissemination,[218] an alpha might be submitted for clearing immediately after execution but not reported until more than 24 hours later, and the clearing agency's duty under new Rule 901(e)(1)(ii) to inform the alpha SDR whether or not the clearing agency has accepted the alpha for clearing could arise before the alpha SDR receives the initial transaction report for the alpha. Therefore, during the interim phase, a registered SDR might receive notice of a clearing agency's rejection of an alpha before receiving the initial transaction report for that alpha.

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[206] Comments pertaining to the reporting of an alpha that is rejected from clearing are discussed in the section immediately following.

[207] ICE Letter at 6.

[208] ISDA/SIFMA Letter at 24.

[209] To address the case where an alpha is rejected from clearing, the Commission is adopting new Rule 902(c)(8), discussed in the subsection immediately below.

[210] *See* ISDA/SIFMA Letter at 24; LCH.Clearnet Letter at 6.

[211] ISDA/SIFMA Letter at 24.

[212] LCH.Clearnet Letter at 6.

[213] *See id.*

[214] Under Rule 901(e)(1)(ii), as adopted herein, a registered clearing agency is required to report whether or not it has accepted a security-based swap for clearing.

[215] In the case of a platform-executed alpha, the security-based swap arises by operation of the platform's rules, and there likely would not be a separate agreement between the counterparties that would allow for amendment in case of rejection, particularly for anonymous trades.

[216] The counterparties could choose to negotiate a new security-based swap, but this would be a different transaction than the alpha that had been rejected from clearing.

[217] A life cycle event is defined, in part, as "with respect to a security-based swap, any event that would result in a change in the information reported to a registered security-based swap data repository under Rule 901 (c). . ." Rule 900(q). Because the resulting bilateral transaction would no longer be intended to be submitted to clearing, the reporting side would be required, among other things, to modify the information previously reported pursuant to Rule 901(c)(6) (whether or not the counterparties intend that the security-based swap be submitted to clearing).

[218] *See* Regulation SBSR Adopting Release, 80 FR at 14616–25.

In this limited case, the Commission believes that no transaction report should be disseminated, and it is adopting a minor revision to existing Rule 902(c) to accomplish that end. Rule 902(c) lists the types of reported information and the types of security-based swap transactions that a registered SDR shall not publicly disseminate. The Commission is adding a new paragraph (c)(8) to Rule 902(c) to prohibit a registered SDR from disseminating "[a]ny information regarding a security-based swap that has been rejected from clearing or rejected by a prime broker [219] if the original transaction report has not yet been publicly disseminated." [220] New Rule 902(c)(8) is designed to avoid public dissemination of an alpha transaction that has been rejected by the clearing agency, if the original transaction report has not already been publicly disseminated by a registered SDR. Rule 902(c)(8) should help minimize public dissemination of events that do not reflect any ongoing market activity.[221]

New Rule 902(c)(8) applies only in cases of rejection prior to public dissemination of the original transaction report of the alpha. When the action of a registered clearing agency results in a termination of an alpha—whether because it was accepted by the clearing agency and replaced by the beta and gamma, or because it was rejected by the clearing agency—the termination of the alpha is a life cycle event of the alpha. If the registered SDR already has publicly disseminated the primary trade information of the alpha, the termination life cycle event also must be publicly disseminated. Rule 907(a)(3) requires a registered SDR to have policies and procedures for flagging the report to indicate that the report is a life cycle event to ensure that market observers can understand that the report represents a revision to a previous transaction.[222] A life cycle event is defined to include the termination of an alpha.

Rule 907(a)(4) requires the policies and procedures of a registered SDR, in relevant part, to identify characteristics of a security-based swap that could, in the fair and reasonable estimation of the registered SDR, cause a person without knowledge of those characteristics to receive a distorted view of the market and to apply condition flags to help prevent a distorted view of the market. The Commission believes that it would be difficult to comply with Rule 907(a)(4) if the condition flags do not provide sufficient information about the specific characteristics to prevent the report from distorting observers' view of the market, including by distinguishing between a termination that results from successful clearing and a termination that results from rejection from clearing. If market observers are not given the ability to distinguish between alphas that terminate because they are successfully cleared and alphas that terminate because they are rejected from clearing, there would be no means for market observers to avoid developing a distorted view of the market.[223] Separate flags for terminations that result from successful clearing of an alpha and terminations that result from rejection from clearing, both of which can be derived from the report of the alpha's clearing disposition provided by a registered clearing agency pursuant to Rule 901(e)(1)(ii), would be appropriate to prevent a distorted view of the market.

K. Scope of Clearing Transactions

One commenter expressed the view that the proposed rule does not address the reporting of trades that are part of a registered clearing agency's end-of-day pricing process.[224] The commenter recommended that these trades be reported by a clearing agency because the clearing agency is "the sole party who holds the necessary information to report trades resulting from downstream clearing processes." [225] In the Regulation SBSR Adopting Release, the Commission noted that the definition of "clearing transaction"—*i.e.*, any security-based swap that has a clearing agency as a direct counterparty [226]—includes "security-based swaps that arise as part of a clearing agency's internal processes, such as security-based swaps used to establish prices for cleared products." [227] In this release, the Commission is adopting new Rule 901(a)(2)(i), as proposed, that makes a registered clearing agency the reporting side for any security-based swap to which it is a counterparty. Thus, a security-based swap that arises from a clearing agency's process for establishing a price for a cleared product must be reported by the registered clearing agency if it is a counterparty to the transaction. Otherwise, the transaction must be reported by the person determined by the reporting hierarchy in existing Rule 901(a)(2)(ii).

L. Reporting of Historical Clearing Transactions

One commenter requested that the Commission clarify that a registered clearing agency "is solely responsible for reporting historical SBS that are clearing transactions." [228] The Commission concurs with this statement. Existing Rule 901(i) provides that, with respect to any historical security-based swap, the reporting side shall report all of the information required by Rules 901(c) and 901(d) to the extent that information about the transaction is available. Under new Rule 901(a)(2)(i), the reporting side for a clearing transaction is the registered clearing agency that is a counterparty to the transaction. The Commission understands that all clearing agencies that are counterparties to historical security-based swaps are "deemed registered" clearing agencies.[229] Therefore, a registered clearing agency is the reporting side for every historical clearing transaction to which it is a counterparty and must report information about such transactions, to the extent that information is available.

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[219] Because rejection by a prime broker has a similar effect to rejection by a clearing agency (*i.e.*, it may result in termination of the initial transaction), the Commission is adopting language relating to prime broker transactions. *See infra* Section VII for additional discussion of prime broker transactions.

[220] The Commission is also making minor technical corrections to paragraphs (c)(6) and (7) of Rule 902(c) to accommodate the addition of (c)(8). The Commission is deleting the word "or" from the end of (c)(6) and the period from the end of (c)(7) and adding "; or" to the end of paragraph (c)(7).

[221] As discussed in Section VII(D), *infra*, a similar situation could arise if a prime broker rejects a security-based swap that has been negotiated between a client and a third-party executing dealer. New Rule 902(c)(8) applies to security-based swaps that have been rejected by a registered clearing agency as well as those that have been rejected by a prime broker.

[222] *See* Regulation SBSR Adopting Release, 80 FR at 14643 ("public reports of life cycle events should allow observers to identify the security-based swap subject to the lifecycle event"). However, the registered SDR may not use the transaction ID for this function and must use other means to link the transactions. *See id.*

[223] For example, assume that two counterparties bilaterally execute a transaction that they wish to clear. The reporting side for the alpha reports the transaction to a registered SDR, which immediately publicly disseminates it. The counterparties then submit the transaction to clearing, but the alpha is rejected because there are clerical errors in the clearing submission report. The registered clearing agency reports the rejection to the alpha SDR, and the alpha SDR disseminates a termination. Shortly thereafter, the alpha counterparties re-execute the transaction, and the reporting side submits a second transaction report to the registered SDR, which immediately publicly disseminates it. The counterparties submit the new transaction to the clearing agency; this time the alpha successfully clears. The registered clearing agency reports this fact to the alpha SDR, which publicly disseminates the termination. If the condition flag indicates only that the alpha is terminated, market observers would likely draw the conclusion that twice as much market activity had occurred than was the case. However, if the condition flags distinguish termination for successful clearing from termination for rejection from clearing, market observers would understand that only the second transaction resulted in ongoing risk positions in the market.

[224] *See* ICE Letter at 9.

[225] *Id.*

[226] *See* Rule 900(g).

[227] 80 FR at 14599.

[228] ISDA/SIFMA Letter at 26.

This commenter also stated that "a clearing agency should not be expected to report the transaction ID of the alpha for an historical clearing transaction since such value may not be readily available." [230] The Commission notes that a registered clearing agency would not be the counterparty to an alpha transaction and thus would incur no duty to report any primary or secondary trade information about the alpha.[231]

IV. Reporting by Platforms

A. Overview

In the Regulation SBSR Proposed Amendments Release, the Commission proposed a new paragraph (1) of Rule 901(a) providing that, if a security-based swap is executed on a platform and will be submitted to clearing (a "platform-executed alpha"), the platform would incur the duty to report. In proposing Rule 901(a)(1), the Commission carefully assessed the transaction information that the platform might not have or might not be able to obtain easily, and proposed to require the platform to report only the information set forth in Rules 901(c) (the primary trade information), 901(d)(1) (the participant ID or execution agent ID for each counterparty, as applicable), 901(d)(9) (the platform ID), and 901(d)(10) (the transaction ID of any related transaction).[232] For platform-executed security-based swaps that will *not* be submitted to clearing, existing Rule 901(a)(2) provides that one of the sides, as determined by that rule's "reporting hierarchy," will have the duty to report.

Five commenters generally supported proposed Rule 901(a)(1).[233] However, two commenters, while not objecting to platforms having reporting duties, argued that the Commission should expand Rule 901(a)(1) to require a platform to report every transaction executed on the platform.[234] In the view of one of these commenters, this approach would eliminate the confusion that could arise if the platform makes an erroneous determination about whether the transaction will be submitted to clearing.[235] The second commenter cautioned that requiring a platform to report only platform-executed transactions that will be submitted to clearing would "depart from current market practice . . . and create different reporting process flows for SEF executed and cleared trades versus SEF executed and uncleared trades." [236] Another commenter, however, recommended that the Commission not expand the scope of Rule 901(a) to require platforms to report all platform-executed security-based swaps.[237]

After carefully considering all the comments, the Commission has determined to adopt Rule 901(a)(1) largely as proposed, but with minor revisions. The revisions, discussed further below, reduce the scope of information that platforms are required to report by eliminating the need for platforms to identify the participation of indirect counterparties. New Rule 901(a)(1) is intended to promote the accuracy and completeness of security-based swap transaction data, while aligning the reporting duty with persons that are best able to carry it out. As the person with the duty to report the transaction, the platform would be able to select the registered SDR to which it reports.[238]

B. A Platform Is Not Required To Report All Transactions Occurring on Its Facilities

If a platform-executed security-based swap will not be submitted to clearing, the platform would have no reporting duty under Regulation SBSR, and the reporting hierarchy in existing Rule 901(a)(2)(ii) would determine which side is the reporting side for the transaction.

One commenter argued that "a platform should report all trades executed on a SB SEF regardless of whether an SB swap will be submitted to clearing." [239] The Commission disagrees. The Commission did not propose and is not adopting an extension to Rule 901(a)(1) that would require a platform to report *all* security-based swaps that are executed on its facilities. Moreover, the approach being adopted by the Commission avoids the need to develop an overly complicated rule that would be needed to identify, with respect to a platform-executed transaction that will *not* be submitted to clearing, what information would be reported by the platform and what information would be reported by one of the sides.[240] The commenter acknowledges that requiring a platform to report uncleared security-based swaps executed on its facilities would necessitate additional reporting by at least one of the sides.[241] As discussed in the subsection immediately below, the Commission believes that the transaction information germane to a platform-executed alpha can and should be reported by the platform.[242] However, a transaction that will not be submitted to clearing is more likely to include bespoke or more counterparty-specific data elements that would be more difficult for the platform to obtain from the counterparties and to report because such non-standardized transactions would not lend themselves to routinized reporting.[243] Rather than adopting an approach that would seek to identify each potential data element and to assign the duty to report it (as between the platform and one of the sides), the Commission instead is adopting an approach that requires the platform to report only those transactions executed on its system that will be submitted to clearing. In cases where a platform-executed transaction will not be submitted to clearing, existing Rule 901(a)(2)(ii) provides that one of the sides will have the duty to report, and this duty is not divided between the platform and the side.

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[229] The Commission understands that ICE Clear Credit and ICE Clear Europe are the only registered clearing agencies that are counterparties to historical security-based swaps that fall within the definition of "clearing transaction" and thus would incur the duty to report those historical transactions. Both ICE Clear Credit LLC and ICE Clear Europe Limited were "deemed registered" in accordance with Title VII of the Dodd-Frank Act. *See* 15 U.S.C. 78q–1(*l*) (the "Deemed Registered Provision"). This provision applies to certain depository institutions that cleared swaps as multilateral clearing organizations and certain derivatives clearing organizations ("DCOs") that cleared swaps pursuant to an exemption from registration as a clearing agency. As a result, ICE Clear Credit LLC, ICE Clear Europe Limited, and the Chicago Mercantile Exchange, Inc. ("CME") were deemed registered with the Commission on July 16, 2011, solely for the purpose of clearing security-based swaps. In 2015 the Commission granted CME's request to withdraw its registration as a clearing agency. *See* Securities Exchange Act Release No. 76678 (December 17, 2015), 80 FR 79983 (December 23, 2015). In its request to withdraw from registration, the CME stated that it had never conducted any clearing activity for security-based swaps. *See* Letter from Larry E. Bergmann and Joseph C. Lombard, on behalf of CME, to Brent J. Fields, Secretary, Commission, dated August 3, 2015.

[230] ISDA/SIFMA Letter at 26.

[231] This commenter also noted that "in some cases a reporting side may be unable to report an historic alpha as before there was no regulatory need to distinguish the alpha from the beta or gamma and some firms may only have booked a position against the clearing agency. In that instance, our understanding is that the historical alpha would not be reportable." *Id.* If it is true that transaction information about a historical alpha no longer exists, there would be no duty to report the alpha pursuant to Rule 901(i). As the Commission stated in the Regulation SBSR Adopting Release, Rule 901(i) requires the reporting of historical security-based swaps only to the extent that information about such transactions is available. *See* 80 FR at 14591.

[232] *See* Regulation SBSR Proposed Amendments Release, 80 FR at 14749–50.

[233] *See* Better Markets Letter at 2, 4 (noting that the "proposal ensures that the reporting party is specified and has all requisite information"); DTCC Letter at 6, 15 (stating that "a platform is best placed to report the alpha trade because it has performed the execution and has all the relevant economic terms, IDs, and timestamps, to report to the [registered SDR]"); ICE Letter at 4; ISDA/SIFMA Letter at 5, 27; LCH.Clearnet Letter at 3.

[234] *See* DTCC Letter at 6; WMBAA Letter at 2.

[235] *See* WMBAA Letter at 2–3. Specifically, the commenter noted that the proposed rule could cause an SDR to receive duplicate reports, "if the platform believes the transaction will be cleared and the counterparties do not clear the trade," or no post-trade report, "if the platform believes the transaction will not be cleared and counterparties clear the trade." *Id.* at 3.

[236] DTCC Letter at 6, n. 14.

[237] *See* ISDA/SIFMA at 27.

[238] This is consistent with the Commission's guidance in the Regulation SBSR Adopting Release that, for transactions subject to the reporting hierarchy, the reporting side may choose the registered SDR to which it makes the report required by Rule 901. *See* 80 FR at 14597–98.

[239] WMBAA Letter at 2.

[240] *See* ISDA/SIFMA Letter at 27 (agreeing with the Commission's approach of not requiring shared reporting of the same transaction and noting that "[u]nder the CFTC Rules, we have experienced the difficulty of a shared obligation for reporting a swap").

The commenter expressed concern that this approach could lead to confusion over reporting obligations when "it is uncertain whether the transaction will be cleared upon execution." [244] A platform can determine whether a particular security-based swap will be submitted to clearing implicitly through the product ID (*e.g.,* if the security-based swap has a product ID of a "made available to trade" product or if the product ID otherwise specifies that the product will be submitted to clearing) or explicitly because the counterparties inform the platform of their intent.[245] Counterparties could signal to a platform that they intend to clear a particular security-based swap using communications infrastructure provided by the platform to submit transaction information to a registered clearing agency or by otherwise specifically informing the platform before or at the time of execution of their intent to submit the trade to clearing. Absent an implicit or explicit indication before or at the time of execution that a particular security-based swap will be submitted to clearing, the platform can reasonably conclude that the transaction will not be submitted to clearing and thus that the platform has no reporting obligation. Thus, if the direct counterparties do not inform the platform before or at the point of execution that they intend to submit the transaction to clearing, the platform incurs no duty to report. In that case, the reporting hierarchy in existing Rule 901(a)(2)(ii) would apply to the security-based swap and the reporting side identified under Rule 901(a)(2)(ii) would be obligated to report the transaction.[246]

Furthermore, the Commission believes that another alternate approach—of requiring all platform-executed transactions, even those that will be submitted to clearing, to be reported by one of the sides and not imposing any reporting duties on platforms—is impractical. As the Commission has noted, platform-executed alphas can be executed anonymously.[247] Although some platform-executed transactions that will be submitted to clearing might not be executed anonymously, the Commission believes that it is more efficient to require the platform to report all security-based swaps executed on that platform that will be submitted to clearing, regardless of whether the counterparties are, in fact, anonymous to each other. The Commission believes that assigning the duty to report to the platform minimizes the number of reporting steps and thus minimizes the possibility of errors or delays in reporting the transaction to a registered SDR. Thus, the Commission believes that all platform-executed transactions that will be submitted to clearing should be reported by the platform. The Commission believes that this approach will be more efficient than if the platform had to assess on a transaction-by-transaction basis whether or not the counterparties are in fact unknown to each other.

C. Data Elements That a Platform Must Report

The Commission continues to believe that platforms should not be required to report information that they do not have or that it would be impractical for them to obtain. In the Regulation SBSR Proposed Amendments Release, the Commission carefully reviewed each data element contemplated by Rules 901(c) and 901(d) and proposed to require platforms to report only those data elements that it believed that would be readily obtainable and germane to the transaction.[248] One commenter stated that "[p]latforms could reasonably be expected to gather and report the primary trade information contained under Rule 901(c)," but cautioned that "requiring platforms to report a subset of the secondary trade information contained under Rule 901(d) will be problematic," specifically noting that the platform could not reasonably be expected to know the guarantors of the direct counterparties.[249] A second commenter also pointed to difficulties with a platform identifying indirect counterparties.[250] In view of these comments, the Commission is adopting, largely as proposed, the list of data elements that the platform must report, but with minor revisions that remove any need for platforms to learn about indirect counterparties.[251]

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[241] *See* WMBAA Letter at 3 ("For uncleared SB swaps, . . . the platform should provide all readily available information, *and the reporting side should be responsible for reporting the information not provided to the SB SEF"*) (emphasis added).

[242] Thus, the sides would have no duty to report anything except missing UICs, as required by existing Rule 906(a). In Rule 906(a), the Commission established a mechanism for obtaining missing UICs from non-reporting sides because it anticipated circumstances when they might be unable or unwilling to provide those UICs to the persons who have the initial reporting duty. *See* Regulation SBSR Adopting Release, 80 FR at 14644.

[243] For example, an uncleared transaction between two counterparties executed on an SB SEF is likely to involve one or more bilateral agreements between the counterparties that govern other facets of their relationship, such as margining and collateral arrangements. The title and date of any such agreement that is incorporated by reference into a security-based swap contract must be reported pursuant to existing Rule 901(d)(4). The Commission does not believe that it would be appropriate to require a platform to obtain this information from the counterparties and to incur the duty for reporting it.

[244] WMBAA Letter at 2.

[245] The Commission notes that the certain execution venues that are registered with the CFTC as swap execution facilities have adopted rules that require swap counterparties to designate whether or not a swap will be submitted to clearing. *See* MarketAxess SEF Rulebook, Rule 905, available at: *http://www.marketaxess.com/pdfs/cds/MKTX_SEF_Rulebook_Effective_08-24-2015.pdf* (last visited May 25, 2016); Bloomberg SEF Rulebook, Rule 533(a), available at: *http://www.bbhub.io/professional/sites/4/BSEF-Rulebook-December-7-2015.pdf,* (last visited May 25, 2016).

[246] The Commission encourages platforms and their participants to develop protocols for determining in advance of execution whether a particular transaction will be submitted to clearing to minimize ambiguity regarding which person—the platform or one of the sides—will have the duty to report under Rule 901(a). If there is ambiguity regarding whether a particular transaction will be submitted to clearing, the counterparties are in the best position to resolve that ambiguity.

[247] *See* Regulation SBSR Proposed Amendments Release, 80 FR at 14748.

[248] *See* 80 FR at 14749–50. One commenter generally agreed that platforms would have the information that the Commission proposed to require them to report. *See* Barnard I at 2.

[249] ICE Letter at 4.

[250] *See* ISDA/SIFMA Letter at 27.

[251] The Commission also is making a minor revision to replace the phrase "the information required by" in proposed Rule 901(a)(1) with "the information set forth in" in final Rule 901(a)(1). This revision is designed to clarify that a platform that incurs a reporting duty under Rule 901(a)(1) must discharge that duty by reporting certain elements that are set forth in Rules 901(c) and 901(d).

The Commission continues to believe that platforms will have or can readily obtain the primary trade information contemplated by Rules 901(c)(1)–(4). For example, the platform will have information that identifies the products that it offers for trading.[252] When a transaction is effected on the platform's facilities, the platform should have the ability to capture the price, the notional amount, and the date and time of execution.[253] As discussed in the subsection immediately above, platforms should be able to ascertain either implicitly (via the product traded) or explicitly (from the counterparties) whether the direct counterparties intend that the security-based swap will be submitted to clearing, as required by Rule 901(c)(6). If the direct counterparties do not inform the platform before or at the point of execution that they intend to submit the transaction to clearing, the platform incurs no duty under Rule 901(c)(6).[254]

The platform will know the direct counterparty on each side of the transaction—or if one side will be allocated among a group of funds or accounts, the execution agent of that side. Therefore, final Rule 901(a)(1) requires the platform to report the counterparty ID or the execution agent ID, as applicable, of each direct counterparty.

The platform also can readily provide its own platform ID, as required by Rule 901(d)(9).

Rule 901(d)(10) applies only if the security-based swap being reported arises from the allocation, termination, novation, or assignment of one or more existing security-based swaps. To the extent that a platform facilitates allocations, terminations, novations, or assignments of existing security-based swaps, the platform would be in a position to require its participants that engage in such exercises to provide the platform with the transaction IDs of the relevant existing security-based swaps, which the platform would report—along with the transaction information about any newly created transaction(s)—pursuant to Rule 901(d)(10).

As noted above, two commenters noted that it would be impractical for platforms to learn the identity of indirect counterparties to transactions effected on their facilities.[255] The Commission agrees that it would be burdensome to require a platform to learn from the direct counterparties, on a trade-by-trade basis, whether either direct counterparty has a guarantor. Furthermore, the Commission now believes that there would be little benefit to imposing such a requirement. A platform-executed security-based swap, if it will be cleared, will be submitted to clearing shortly after execution and thus will have only a short lifespan. Shortly, or perhaps even immediately, after being submitted to clearing, it will likely either be terminated because it is accepted for clearing or terminated because it is rejected from clearing. In either case, the potential exposure of a guarantor of the alpha transaction—if there is a guarantor—is likely to be fleeting. In view of the potential burdens that a requirement to report indirect counterparties could place on platforms against only marginal benefits, the Commission has determined not to adopt any requirement for platforms to report indirect counterparties.[256]

Existing Rule 901(c)(5) requires reporting of whether both sides of a security-based swap include a registered security-based swap dealer. One of the commenters who argued for the removal of the requirement for platforms to report indirect counterparties also noted that it would be difficult for platforms to comply with Rule 901(c)(5) if a registered security-based swap dealer was an indirect counterparty.[257] The Commission agrees. Therefore, for the same reasons that it has decided not to adopt a requirement for platforms to report whether either direct counterparty has a guarantor, the Commission has revised final Rule 901(a)(1) to require a platform to indicate only when both *direct counterparties* of a security-based swap are registered security-based swap dealers—not, as originally proposed, if a registered security-based swap dealer is present on both sides (*e.g.,* as a guarantor). A platform will be able to learn from publicly available sources when its participants who effect transactions as direct counterparties are registered as security-based swap dealers.[258]

D. Platform Duty To Report Secondary Trade Information

Final Rule 901(a)(1) makes clear that the only secondary trade information that a platform must report is the counterparty ID of each direct counterparty (or execution agent, if applicable);[259] the platform ID;[260] and the transaction ID of the prior security-based swap if the platform-executed security-based swap results from the allocation, termination, novation, or assignment of the prior transaction.[261]

One commenter expressed concern about a platform having to report other secondary trade information, such as the title and date of any agreements incorporated by reference into the security-based swap contract.[262] Rule 901(a)(1), both as proposed and as adopted, requires a platform to report only the secondary trade information specifically enumerated in the rule. The agreements contemplated by Rule 901(d)(4) are not so enumerated.[263]

E. Platform Has No Duty To Report Life Cycle Events

One commenter argued that platforms should have no duty to report life cycle event information because platforms have no involvement in a security-based swap after execution and would not have access to such information.[264] The Commission agrees. Therefore, the Commission did not propose and is not adopting a requirement for platforms to report any life cycle events.

Existing Rule 901(e)(1)(i) provides that most life cycle events (and adjustments due to life cycle events) must be reported *by the reporting side.* A platform is not a counterparty to a security-based swap and thus cannot be a reporting side. Therefore, existing Rule 901(e)(1)(i), by its terms, imposes no duty on platforms to report life cycle events. Furthermore, Rule 901(e)(1) includes one exception to the general rule that the reporting side must report life cycle events: New paragraph (e)(1)(ii), as adopted today, requires the registered clearing agency to which the platform-executed alpha is submitted to report to the alpha SDR whether or not it has accepted a security-based swap for clearing. The Commission believes that these are the only life cycle events germane to a platform-executed alpha—the transaction will either be terminated because it is accepted for clearing or terminated because it is rejected from clearing—and therefore is not imposing any requirement on the platform or either of the sides to report additional types of life cycle events for platform-executed alphas.

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[252] *See* Rule 901(c)(1).

[253] *See* Rule 901(c)(2)–(4).

[254] The Commission believes that this approach responds to the commenter who noted that, in some instances, a platform might not know the intent of the counterparties and thus would have difficulty complying with Rule 901(c)(6). *See* WMBAA Letter at 3.

[255] *See* ICE Letter at 4; ISDA/SIFMA Letter at 27 (stating that "[a] platform will not likely have advance access to complete information pertaining to whether there is an indirect counterparty on either side of the transaction," and that building a mechanism to capture the existence of indirect counterparties "must be factored into the implementation timeframe for platforms").

[256] This revision in final Rule 901(a)(1) does not affect the existing requirements for reporting a platform-executed transaction that *will not* be submitted to clearing. Such a transaction is governed by existing Rule 901(a)(2)(ii), which requires one of the sides to be the reporting side. The reporting side must report, among other things, all of the information required by Rule 901(d) including, as applicable, the identity of its own guarantor and any guarantor of the direct counterparty on the other side. Reporting of the guarantor(s) of a security-based swap will assist the Commission and other relevant authorities in monitoring the ongoing exposures of market participants.

[257] *See* ISDA/SIFMA Letter at 27.

[258] *See* SBS Entity Registration Adopting Release, 80 FR at 48972 ("The Commission intends to notify entities electronically through the EDGAR system when registration is granted, and will make information regarding registration status publicly available on EDGAR").

[259] *See* Rule 901(d)(1). As noted above, final Rule 901(a)(1) requires a platform to report the counterparty IDs only of the direct counterparties to the transaction, not of any indirect counterparties.

[260] *See* Rule 901(d)(9).

[261] *See* Rule 901(d)(10).

[262] *See* WMBAA Letter at 4 (referencing requirement in Rule 901(d)(4)).

[263] *See* ISDA/SIFMA Letter at 27 (correctly observing that the Commission did not propose to require platforms to report agreement information).

[264] *See* WMBAA Letter at 4.

F. Implementation Issues

One commenter encouraged the Commission "to allow the use of existing reporting technology and reporting architecture to reduce the amount of additional technology investment required to comply" with any reporting obligations.[265] This commenter further requested that the Commission "make clear in its final rules that platforms have discretion to determine the most appropriate technological manner in which they comply with the Commission's rules."[266] The Commission has been sensitive to the current state of the security-based swap industry and, in particular, the technological baseline that is utilized by market participants and infrastructure providers to carry out business and regulatory functions. The Commission has sought to adopt final rules that minimize changes to systems and processes so far as they can be adapted to new reporting duties, while recognizing that new systems or processes, or fairly significant revisions to existing systems or processes, might be necessary in some cases.

The Commission acknowledges that Rule 901(a)(1) will require platforms to develop, test, implement, and maintain technology to ensure connectivity to at least one registered SDR.[267] Rule 901(a)(1) does not specify the reporting technology or reporting architecture for platforms to use, and platforms may use their existing technology and architecture to reduce the amount of additional technology investment required to comply with the rule. Moreover, the Commission affirms that platforms may retain third-party service providers to facilitate compliance with their reporting obligations. The Commission notes that platforms are no different from other persons having a duty to report that elect to use an agent to carry out that function; the person with the reporting duty would retain responsibility under Regulation SBSR for providing the required information in the required format.[268]

Finally, this commenter also urged the Commission to "clearly outline the specific data fields, and permissible formats for reporting those data fields, required for post-trade reporting."[269] When it adopted Regulation SBSR, the Commission took the approach of generally requiring reporting of general categories of data (such as the "price")[270] while requiring registered SDRs to establish and maintain written policies and procedures that specify the manner in which persons having a duty to report must provide security-based swap transaction data to the SDR.[271] In the Regulation SBSR Adopting Release, the Commission considered whether to prescribe formats for the data elements required by Regulation SBSR, and concluded that "it is neither necessary or appropriate to mandate a fixed schedule of data elements to be reported, or a single format or language for reporting such elements to a registered SDR."[272] In the Regulation SBSR Proposed Amendments Release, the Commission did not propose a new approach for specifying how the required data elements must be reported to a registered SDR, and declines to adopt a new approach here.[273]

G. Reporting Duty Applies Even to Unregistered Platforms

New Rule 901(a)(1) imposes a reporting duty on any "platform" if a security-based swap that will be submitted to clearing is executed on the platform. One commenter requested the Commission to clarify "whether an alpha SBS entered into via an execution venue in advance of its registration or exemption as a national securities exchange or security-based swap execution facility is required to be reported to one of the sides."[274] The commenter stated that "[i]deally the registration or exemption of platforms would precede the compliance date for reporting under [Regulation] SBSR. Otherwise, the industry will need to transition the reporting responsibility which may lead to gaps or duplications in reporting since the relevant static data and any system architectural changes will not occur simultaneously."[275] The commenter argued, in the alternative, that "the Commission should exempt alphas from reporting in advance of platform registration."[276] A second commenter stated that it "is uncertain as to how the reporting obligations for a platform under Regulation SBSR would be fulfilled if the compliance dates are triggered before the Commission implements SB swap trading rules."[277]

In the Regulation SBSR Adopting Release, the Commission explained that there are certain entities that currently meet the definition of "security-based swap execution facility" but that are not yet registered with the Commission and will not have a mechanism for registering as SB SEFs until the Commission adopts final rules governing the registration and core principles of SB SEFs. These entities currently operate pursuant to an exemption from certain provisions of the Exchange Act.[278] To ensure that transactions that occur on such exempt SB SEFs are captured by Regulation

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[265] *See* WMBAA Letter at 3.

[266] *Id.*

[267] *See* WMBAA Letter at 3.

[268] *See* Regulation SBSR Adopting Release, 80 FR at 14602.

[269] WMBAA Letter at 2.

[270] *See* Rule 901(c)(3).

[271] *See* Rules 907(a)(1) and 907(a)(2). The Commission did, however, require reporting of some specific data elements. *See, e.g.,* Rule 901(c)(6) (requiring reporting of whether the direct counterparties intend that the security-based swap will be submitted to clearing); Rule 901(d)(9) (requiring reporting of the platform ID, if applicable).

[272] 80 FR at 14595. The Commission noted, furthermore, that new security-based swap products are likely to develop over time and a rule establishing a fixed schedule of data elements could become obsolete as new data elements might become necessary to reflect material economic terms of new security-based swap products. *See id.*

[273] The Commission notes, however, that it has proposed an amendment to Rule 13n–4(a)(5) under the Exchange Act, 17 CFR 240.13n–4(a)(5), that would specify the form and manner with which SDRs will be required to make security-based swap data available to the Commission. *See* Securities Exchange Act Release No. 76624 (December 11, 2015), 80 FR 79757 (December 23, 2015).

[274] ISDA/SIFMA Letter at 28.

[275] *Id.*

[276] *Id.*

[277] WMBAA Letter at 5.

[278] *See* Securities Exchange Act Release No. 64795 (July 1, 2011), 76 FR 39927 (July 7, 2011). In this order, the Commission granted entities that meet the statutory definition of "exchange" solely due to their activities relating to security-based swaps a temporary exemption from the requirement to register as a national securities exchange in Sections 5 and 6 of the Exchange Act, 15 U.S.C. 78e and 78f. This included entities that would meet the statutory definition of "security-based swap execution facility" but that otherwise would not be subject to the requirements under Sections 5 and 6 of the Exchange Act.

SBSR, existing Rule 900(v) defines “platform” as “a national securities exchange or security-based swap execution facility that is registered *or exempt from registration*” (emphasis added). Therefore, the Commission does not believe that it is necessary, as the commenter suggests, to transfer reporting duties from the platform to one of the sides, or to exempt alphas from reporting entirely, until the Commission adopts registration rules for SB SEFs. Doing so could significantly delay the benefits of regulatory reporting and public dissemination of platform-executed alpha transactions. Furthermore, the Commission understands that, although platforms for security-based swaps might not yet be registered with the Commission, they likely already possess significant post-trade processing capabilities because of their activities in the swaps market, which subjects them to reporting duties under CFTC rules.[279] In any event, unregistered platforms will have an extended period in which to prepare for their reporting duties under Regulation SBSR, as new transactions in an asset class will not have to be reported until at least six months after the first SDR that can accept transactions in that asset class registers with the Commission.[280]

V. Additional Matters Concerning Platforms and Registered Clearing Agencies

A. Extending “Participant” Status

Existing Rule 901(h) requires “a reporting side” to electronically transmit the information required by Rule 901 in a format required by the registered SDR. In the Regulation SBSR Proposed Amendments Release, the Commission proposed to replace the term “reporting side” in Rule 901(h) with the phrase “person having a duty to report.” Under Rule 901(a), as amended by this release, a platform or registered clearing agency might incur a reporting duty even if it is not one of the sides to the transaction.[281] All persons who have a duty to report under Regulation SBSR—*i.e.,* platforms, reporting sides, and registered clearing agencies that must report whether or not a security-based swap is accepted for clearing—must electronically transmit the information required by Rule 901 in a format required by the registered SDR. Replacing “reporting side” with “person having the duty to report” in Rule 901(h) extends this requirement to all persons with reporting duties, even if they are not one of the sides. The Commission received no comments that specifically addressed the amendment to Rule 901(h)[282] and is adopting this amendment as proposed.

Under existing Rule 900(u), platforms and registered clearing agencies would not be participants of registered SDRs solely as a result of having a duty to report security-based swap transaction information pursuant to Rule 901(a)(1) or 901(e)(1)(ii), respectively.[283] In the Regulation SBSR Proposed Amendments Release, the Commission expressed the preliminary view that platforms and registered clearing agencies should be participants of any registered SDR to which they report security-based swap transaction information on a mandatory basis. Consistent with this view, the Commission proposed to amend the definition of “participant” in Rule 900(u) to include a platform that is required to report a security-based swap pursuant to Rule 901(a)(1) or a registered clearing agency that is required to report a life cycle event pursuant to Rule 901(e)(1)(ii).[284]

One commenter expressed general support for requiring platforms and clearing agencies to become participants of the registered SDRs to which they report.[285] A second commenter agreed that a clearing agency or platform must be a participant of a registered SDR to which it reports to ensure that reports are submitted in a format required by the registered SDR.[286] The second commenter, however, also expressed its understanding “that in this context, participant means a registered user of an SDR, submitting data in the format as requested by the SDR, rather than a ‘participant’ as defined in Final SBSR.”[287] A third commenter agreed that platforms should be required to report transaction data to a registered SDR “in a format required by that registered SDR”; however, the commenter “does not believe that it should be required to become a member of an SDR.”[288] A fourth commenter stated that, although a clearing agency “should execute an agreement outlining the requirements to report termination messages” to the alpha SDR, the clearing agency should not become a full participant of the alpha SDR because it is not a counterparty to the alpha.[289] This commenter also argued that the clearing agency “should not incur SDR fees to report alpha termination messages.”[290]

After carefully considering the comments, the Commission is adopting the amendment to Rule 900(u) as proposed. Conferring “participant” status on these additional entities subjects them to the requirement in Rule 906(c), as amended herein,[291] for enumerated participants to establish, maintain, and enforce written policies and procedures that are reasonably designed to ensure that they comply with any obligations to report information to a registered SDR in a manner consistent with Regulation SBSR. The Commission believes that these policies and procedures will increase the accuracy and reliability of information reported to registered SDRs. Without written policies and procedures for carrying out their reporting obligations, clearing agencies and the other entities enumerated in Rule 906(c), as amended, might depend too heavily on key individuals or *ad hoc* and unreliable processes. Written policies and procedures, however, can be shared throughout an organization and generally should be independent of any specific individuals. Requiring clearing agencies, as well as the other participants enumerated in Rule 906(c), to adopt and maintain written policies and procedures relevant to their reporting responsibilities should help to improve the degree and quality of overall compliance with the reporting requirements of Regulation SBSR. Periodic review of these policies and procedures, as required by Rule 906(c), should help to ensure that these policies and procedures remain well-functioning over time.

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[279] *See* 17 CFR 43.8(h) (reporting by SEF or designated contract market).

[280] *See infra* Section X (discussing compliance dates).

[281] The Commission proposed to expand Rule 908(b) to include all platforms and registered clearing agencies. This amendment to Rule 908(b) is discussed in Section IX, *infra.*

[282] *But see* ISDA/SIFMA Letter at 29 (endorsing a similar amendment to Rule 905(a)(1) that expands that rule from “the reporting side” to “the person having the duty to report”).

[283] Existing Rule 900(u) provides that a “[p]articipant, with respect to a registered security-based swap data repository, means a counterparty, that meets the criteria of [Rule 908(b)], of a security-based swap that is reported to that registered security-based swap data repository to satisfy an obligation under [Rule 901(a)].”

[284] A registered clearing agency that is required to report a clearing transaction pursuant to Rule 901(a)(2)(i) is a counterparty to that security-based swap and is thus covered by the existing definition of “participant.”

[285] *See* DTCC Letter at 5–6, 17 (stating that “the clearing agency should become an onboarded participant of the SB SDR and adhere to the policy and procedures to report data in the format required by the SB SDR. In this regard, separate accommodations should not be made for clearing agencies, which should be required to comply with an SB SDR's policies and procedures to the same extent as other market participants”).

[286] *See* ISDA/SIFMA Letter at 24, 27.

[287] *Id.* at 24.

[288] WMBAA Letter at 4.

[289] ICE Letter at 6.

[290] *Id.*

[291] *See infra* Section V(E).

A registered clearing agency that clears security-based swaps or a platform that executes security-based swaps that will be submitted to clearing incurs reporting duties under Regulation SBSR, which requires the platform or registered clearing agency, among other things, to submit transaction information to one or more registered SDRs. As a result of the amendment to Rule 900(u) being adopted today, the platform or registered clearing agency automatically becomes a "participant"—under Regulation SBSR—of any SDR to which it submits transaction information on a mandatory basis. The Commission notes, however, that "participant" status under Rule 900(u) does not require a platform or registered clearing agency to sign a formal participant agreement with a registered SDR or to establish connectivity sufficient to report all of the primary and secondary trade information of a security-based swap.[292] A registered SDR may impose certain obligations on persons who utilize the SDR's services, regardless of whether such persons are deemed "participants" under Regulation SBSR. For example, an SDR may impose fees on such persons for submitting data.[293]

B. Examples of Reporting Workflows Involving Platforms and Registered Clearing Agencies

The following examples illustrate the reporting process for alpha, beta, and gamma security-based swaps, assuming an agency model of clearing under which a counterparty to an alpha security-based swap becomes a direct counterparty to a subsequent clearing transaction:[294]

- *Example 1.* A registered security-based swap dealer enters into a security-based swap with a private fund. The transaction is not executed on a platform. The counterparties intend to clear the transaction (*i.e.,* the transaction is an alpha). Neither side has a guarantor with respect to the alpha, and both direct counterparties are U.S. persons.
  - ○ The registered security-based swap dealer is the reporting side under existing Rule 901(a)(2)(ii) and must report this alpha transaction to a registered SDR (and may choose the registered SDR).
  - ○ New Rule 901(a)(3) requires the registered security-based swap dealer, as the reporting side of the alpha transaction, to promptly provide to the registered clearing agency the transaction ID of the alpha and the identity of the alpha SDR.
  - ○ If the registered clearing agency accepts the alpha for clearing and terminates the alpha, two clearing transactions—a beta (between the registered security-based swap dealer and the registered clearing agency) and a gamma (between the registered clearing agency and the private fund)—take its place.
  - ○ New Rule 901(e)(1)(ii) requires the registered clearing agency to report to the alpha SDR that it accepted the transaction for clearing.
  - ○ Under new Rule 901(a)(2)(i), the registered clearing agency is the reporting side for each of the beta and the gamma. Therefore, the registered clearing agency must report the beta and gamma to a registered SDR (and the clearing agency may select the registered SDR). The report for each of the beta and the gamma must include the transaction ID of the alpha, as required by existing Rule 901(d)(10).
- *Example 2.* Same facts as Example 1, except that the private fund and the registered security-based swap dealer transact on an SB SEF.
  - ○ New Rule 901(a)(1) requires the SB SEF to report the alpha transaction (and allows the SB SEF to choose the registered SDR).
  - ○ After the alpha has been submitted to clearing, new Rule 901(a)(3) requires the SB SEF to promptly report to the registered clearing agency the transaction ID of the alpha and the identity of the alpha SDR.
  - ○ Once the alpha is submitted to clearing, the reporting workflows are the same as in Example 1.

C. Amendments to Rule 905(a)

Existing Rule 905(a) provides a mechanism for reporting corrections of previously submitted security-based swap transaction information.[295] Rule 905(a)(1) requires a non-reporting side that discovers an error in a previously submitted security-based swap to promptly notify "the reporting side" of the error.[296] Under existing Rule 905(a)(2), once "the reporting side" receives notification of an error from the non-reporting side or discovers an error on its own, "the reporting side" is required to promptly submit an amended report containing the corrected information to the registered SDR that received the erroneous transaction report.

In the Regulation SBSR Proposed Amendments Release, the Commission proposed—and today is adopting—amendments to Rule 901(a) that require platforms and registered clearing agencies to report certain transaction information. To preserve the principle in existing Rule 905(a) that the person responsible for reporting information also should have responsibilities for correcting errors, the Commission proposed to replace the term "reporting side" in existing Rules 905(a)(1) and 905(a)(2) with the phrase "person having a duty to report." This amendment was necessitated by the fact that a platform—and a registered clearing agency, when it has the duty to report whether or not it has accepted a security-based swap for clearing—is not a side to the transaction, and thus is not covered by existing Rule 905(a).

Under the proposed amendment to Rule 905(a)(1), a person that is not the reporting side who discovers an error in a previously submitted security-based swap would be required to promptly notify "the person having the duty to report" of the error. Under the proposed amendment to Rule 905(a)(2), "the person having the duty to report" a security-based swap would be required to correct previously reported erroneous information with respect to that security-based swap if it discovers an error or if it receives notification of an error from a counterparty. Four commenters expressed general support for the proposed amendments to Rule 905(a).[297]

After carefully considering the comments received, the Commission is adopting the amendments to Rule 905(a) as proposed. The Commission believes that, in light of the amendments to Rule 901(a) that also are being adopted today,[298] Rule 905(a) is necessary to account for the possibility that a person who is not a counterparty and is thus not on either side of the transaction could have a duty to report. Thus, a platform or registered clearing agency (when the clearing agency is reporting whether or not it has accepted an alpha for clearing and thus is not the reporting side of the alpha) can incur a duty to report a correction, because it also can incur the initial duty to report the relevant information.

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[292] At the same time, nothing in Regulation SBSR prevents a platform or registered clearing agency from signing such a participation agreement.

[293] *See supra* note 191 and accompanying text. However, an SDR must offer fair, open, and not unreasonably discriminatory access to users of its services and ensure that any fees that it charges are fair and reasonable and not unreasonably discriminatory. *See* Rules 13n–4(c)(1)(i) and 13n–4(c)(1)(iii) under the Exchange Act, 17 CFR 240.13n–4(c)(1)(i) and 240.13n–4(c)(1)(iii).

[294] Because clearing of security-based swaps in the United States is still evolving, other models of clearing might emerge where customers would not become direct counterparties of a registered clearing agency. *See supra* Section III(A)(1) (discussing the clearing process in the United States).

[295] *See* Regulation SBSR Adopting Release, 80 FR at 14641–42.

[296] *See* Regulation SBSR Adopting Release, 80 FR at 14681.

[297] *See* DTCC Letter at 18; LCH.Clearnet Letter at 11; ISDA/SIFMA Letter at 29; WMBAA Letter at 5. Another commenter acknowledged that the proposed amendments are "technical changes to the rules to incorporate these new reporting participants," but made no further commentary on the proposed amendments to Rule 905(a). *See* Better Markets Letter at 3–4.

[298] *See supra* Section II(B).

One commenter, discussing general difficulties in making non-reporting sides become "onboarded users" of registered SDRs, stated that only reporting sides—who presumably would be onboarded users—should be responsible for amending errors and omissions associated with previously submitted security-based swaps.[299] The Commission agrees that the person having the duty to report the initial transaction should be responsible for amending errors and omissions. There is no scenario under Rule 905(a), as amended, in which a non-reporting side must report anything to a registered SDR. If a non-reporting side discovers an error, Rule 905(a)(1) requires the non-reporting side to inform the person who had a duty to report the initial transaction—which could be a platform, a registered clearing agency, or the reporting side—not the registered SDR.

A second commenter expressed the view that "[w]hen a correction is made to a trade which has already been accepted by a registered clearing agency or prime broker, then that party must also notify the registered clearing agency or prime broker of the correction." [300] Nothing in Regulation SBSR requires a person to notify the registered clearing agency or prime broker of a correction after the person reports the correction to a registered SDR. Rule 905(a) is concerned with maintaining accurate information in registered SDRs. The acceptance of a security-based swap by a registered clearing agency or a prime broker (in the case of a three-legged prime brokerage structure) terminates the initial transaction and results in the creation of new security-based swaps pursuant to the rules of the relevant registered clearing agency or the terms of the prime brokerage arrangement, respectively.[301] Rule 905(a) requires that, if the person having the duty to report the original transaction becomes aware of erroneous information in the report of the transaction, that person must submit a correction to the registered SDR. If the sides of the security-based swap also provided incorrect information about the initial transaction to the registered clearing agency or prime broker, the sides presumably would follow the procedures required by the registered clearing agency or the prime brokerage arrangement to correct the error—but nothing in Regulation SBSR compels that result.

D. Requirements Related to Participant Providing Ultimate Parent and Affiliate Information to Registered SDR

As described in Section V(A), *supra,* the Commission is adopting, as proposed, an amendment to the definition of "participant" in Rule 900(u) to include platforms that are required to report platform-executed security-based swaps that will be submitted to clearing and registered clearing agencies that are required to report whether or not an alpha is accepted for clearing. Existing Rule 906(b) requires each participant—as defined by Rule 900(u)—of a registered SDR to provide the SDR with information sufficient to identify any affiliate(s) of the participant that also are participants of the SDR and any ultimate parent(s) of the participant.[302] By amending Rule 900(u) to make platforms and registered clearing agencies participants, these entities would become subject to Rule 906(b). In the Regulation SBSR Proposed Amendments Release, however, the Commission proposed to amend Rule 906(b) to exclude platforms or registered clearing agencies from the requirement to provide information about affiliates and ultimate parents to an SDR.

Three commenters expressed support for the Commission's proposal to exempt platforms and registered clearing agencies from the obligations of Rule 906(b).[303] The Commission continues to believe that platforms and registered clearing agencies should be exempt from the obligations of Rule 906(b) and is adopting the amendment to Rule 906(b) as proposed.

The Commission also proposed to make a similar amendment to existing Rule 907(a)(6), which requires a registered SDR to have policies and procedures "[f]or periodically obtaining from each participant information that identifies the participant's ultimate parent(s) and any participant(s) with which the participant is affiliated, using ultimate parent IDs and counterparty IDs." The Commission proposed to amend Rule 907(a)(6) to require registered SDRs to have policies and procedures to obtain this information from each participant "other than a platform or a registered clearing agency." One commenter supported the Commission's proposal.[304] The Commission continues to believe that this amendment to Rule 907(a)(6) is appropriate and is adopting the amendment as proposed.

One commenter asked the Commission to exclude from Rule 906(b) transactions that include an execution agent ID.[305] The commenter stated: "Aggregation across affiliated entities under a common parent makes the most sense from a regulatory or systemic risk perspective where there is coordinated trading activity and/or the risk of such swap positions is borne by the parent under an explicit or implicit guarantee. In the context of asset management, neither is typically present. For separate account clients, virtually all the asset management assignments undertaken by our members are on a discretionary basis . . . As a result, the separate account client (let alone its affiliates or parent) would not be responsible under its trading contracts for trading losses incurred by a manager acting on its behalf beyond the assets it has provided to that manager." [306]

Rule 906(b) is designed to facilitate the Commission's ability to measure security-based swap exposure within the same ownership group. The Commission believes that requiring the funds and accounts described in the commenter's letter to report parent and affiliate information would not serve this goal. Accordingly, the Commission is amending Rule 906(b) to exclude externally managed investment vehicles from the requirement to provide ultimate parent and affiliate information to any registered SDR of which it is a participant.[307] The Commission is not acting upon the commenter's specific suggestion to base an exclusion on the fact that the transaction reports submitted by a fund includes an ID of an execution agent. There could be situations where a corporate entity within a group that Rule 906(b) is designed to cover might use an execution agent and thus would be required to report an execution agent ID. Therefore, basing an exclusion from Rule 906(b) on the use of an execution agent ID would be broader than necessary. The Commission believes instead that an exclusion for externally managed investment vehicles is well tailored to satisfy the concerns raised by the commenter while minimizing the risk of unduly broadening the exclusion. In light of this amendment to Rule 906(b), the Commission is making a conforming change to Rule 907(a)(6). Under Rule 907(a)(6), as amended, a registered SDR need not include in its policies and procedures for obtaining ultimate parent and affiliate information a mechanism for obtaining such information from externally managed investment vehicles.

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[299] *See* DTCC/ICE/CME Letter at 2 (also stating that requiring reporting sides to amend errors and omissions would support "current operational workflows since the reporting side is the only party with a contractual relationship with the non-reporting side as it relates to the trade details").

[300] LCH.Clearnet Letter at 11.

[301] *See supra* Section III(E) (discussing clearing process in the agency model of clearing); *infra* Section VII(B) (discussing prime brokerage workflows).

[302] *See* Regulation SBSR Adopting Release, 80 FR at 14645.

[303] *See* LCH.Clearnet Letter at 11; ISDA/SIFMA Letter at 29; WMBAA Letter at 5.

[304] ISDA/SIFMA Letter at 29 ("as we support the assignment of reporting duties to platforms and clearing agencies, [we] also agree with the conforming changes to . . . Rule 907(a)(6)").

[305] *See* SIFMA–AMG II at 3–4. The commenter appears to be of the view that ultimate parent IDs and affiliate IDs are fields that must be included in reports of individual transactions. *See id.* at 3 ("AMG requests clarification that the parent and affiliate fields are not applicable (or 'N/A') for a trade if the trade report includes an execution agent's ID"). The Commission notes, however, that a participant's ultimate parent and affiliate information must be disclosed to the registered SDR of which it is a participant in a separate report, not in individual transaction reports.

[306] *Id.* at 3–4. *See also id.* at 4 ("There is even less reason to require identification of the affiliates or parent of a collective investment vehicle. While funds in the same complex could be viewed as affiliated for certain purposes, aggregating swap positions across funds where recourse is legally and contractually limited would be misleading from a systemic risk and regulatory oversight perspective").

The Commission declines to grant the commenter's request to exclude accounts from Rule 906(b). Although, as the commenter indicates, the parent(s) or affiliate(s) of a separate account client may not be responsible for losses incurred in the account, the security-based swap exposure in multiple accounts of a parent would be relevant to understanding the total exposure within the same ownership group. Thus, an account's reporting of its parent and affiliate information will serve the purposes of Rule 906(b) by assisting the Commission in monitoring enterprise-wide risks related to security-based swaps.

E. Additional Entities Must Have Policies and Procedures for Supporting Their Reporting Duties

Existing Rule 906(c) requires each participant of a registered SDR that is a registered security-based swap dealer or registered major security-based swap participant to establish, maintain, and enforce written policies and procedures that are reasonably designed to ensure that the participant complies with any obligations to report information to a registered SDR in a manner consistent with Regulation SBSR. Rule 906(c) also requires each registered security-based swap dealer and registered major security-based swap participant to review and update its policies and procedures at least annually.

In the Regulation SBSR Proposed Amendments Release, the Commission proposed to extend the requirements of Rule 906(c) to registered clearing agencies and platforms that are participants of a registered SDR.[308] Four commenters generally supported this amendment.[309]

In the U.S. Activity Proposal, the Commission proposed to extend the requirements of Rule 906(c) to any registered broker-dealer that incurs reporting obligations solely because it effects transactions between two unregistered non-U.S. persons that do not fall within proposed Rule 908(b)(5). The Commission received no comments regarding the proposed amendment to Rule 906(c) for registered broker-dealers. The Commission continues to believe that this amendment is appropriate and is adopting the amendment as proposed.[310]

One commenter stated that the Commission should expand Rule 906(c) "to include all parties with reporting obligations under Regulation SBSR, including platforms and registered clearing agencies." [311] While the Commission is expanding Rule 906(c) to include platforms and registered clearing agencies, the Commission did not propose and is not adopting any amendment to expand Rule 906(c) to include "all parties" with reporting obligations under Regulation SBSR, which would include unregistered persons. Regulation SBSR was designed to minimize, to the extent feasible, instances where unregistered persons have the primary duty to report security-based swaps; an unregistered person that is a participant of a registered SDR in most cases will have only limited duties under Regulation SBSR, such as the duty to report UIC information pursuant to Rule 906(a).[312] The Commission does not believe that it is appropriate to require unregistered persons to establish policies and procedures to support this limited reporting function.

VI. Reporting and Public Dissemination of Security-Based Swaps Involving Allocation

A. Background

The Regulation SBSR Adopting Release provides guidance for the reporting of certain security-based swaps executed by an asset manager on behalf of multiple clients—transactions involving what are sometimes referred to as "bunched orders." [313] That release

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[307] In the Cross-Border Adopting Release, the Commission added an express reference to "investment vehicle" in the non-exclusive list of legal persons that could fall within the final definition of "U.S. person" in Rule 3a71–3(a)(4) under the Exchange Act, 17 CFR 240.3a71–3(a)(4). The Commission observed that investment vehicles are commonly established as partnerships, trusts, or limited liability entities and required that an investment vehicle will be treated as a U.S. person for purposes of Title VII if it is organized, incorporated, or established under the laws of the United States or has its principal place of business in the United States. *See* Cross-Border Adopting Release, 79 FR at 47307. Thus, an investment vehicle—despite being incorporated, organized, or established under the laws of a foreign jurisdiction—would be a U.S. person if it is externally managed from the United States, *i.e.,* its operations "are primarily directed, controlled, and coordinated from a location within the United States." *Id.* at 47310.

[308] *See* 80 FR at 14759.

[309] *See* Better Markets Letter at 6; DTCC Letter at 18; ISDA/SIFMA Letter at 29; LCH.Clearnet Letter at 11.

[310] Existing Rule 906(c) is titled: "Policies and procedures of registered security-based swap dealers and registered major security-based swap participants." As the Commission has proposed to subject various other types of persons to Rule 906(c), the Commission also proposed to revise the title to "Policies and procedures to support reporting compliance." The Commission is adopting the amended title.

[311] LCH.Clearnet Letter at 11.

[312] Existing Rule 906(a) applies to all participants of a registered SDR, including a participant that is the non-reporting side of a security-based swap reported to the registered SDR on a mandatory basis. Rule 906(a), in relevant part, requires a participant of a registered SDR, with respect to a transaction to which it is a direct counterparty, to provide the SDR with any UICs that the SDR lacks, including a counterparty ID "or (if applicable), the broker ID, branch ID, execution agent ID, desk ID, and trader ID." In the Regulation SBSR Adopting Release, the Commission explained why it adopted the term "trading desk" and "trading desk ID" rather than, as in earlier proposed versions, "desk" and "desk ID." *See* 80 FR at 14583–84. However, in one place in Rule 906(a), the Commission failed to revise the term "desk ID" to "trading desk ID" even though it had done so in another place in Rule 906(a). Therefore, the Commission in this release is adopting a technical correction to Rule 906(a) to utilize the term "trading desk ID" in both places. In addition, one commenter requested clarification "that trading desk ID and trader ID fields are not applicable (or 'N/A') for trades entered into by an execution agent." SIFMA–AMG II at 2. Based on the rule text, the Commission believes that this is a reasonable interpretation of Rule 906(a).

[313] *See* Regulation SBSR Adopting Release, 80 FR at 14625–27. The Commission recognizes that market participants may use a variety of other terms to refer to such transactions, including "blocks," "parent/child" transactions, and "splits." The Commission has determined to use a single term, "bunched orders," for purposes of this release, as this appears to be a widely accepted term. *See, e.g.,* "Bunched orders challenge SEFs," MarketsMedia (March 25, 2014), available at *http://marketsmedia.com/bunched-orders-challenge-sefs/* (last visited May 25, 2016); "Cleared bunched trades could become mandatory rule," *Futures and Options World* (October 31, 2013), available at *http://www.fow.com/3273356/Cleared-bunched-*

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explained how Regulation SBSR applies to executed bunched orders that are subject to the reporting hierarchy in existing Rule 901(a)(2)(ii), including bunched order alphas that are not executed on a platform and platform-executed bunched orders that will not be submitted to clearing. That release also explained how Regulation SBSR applies to the security-based swaps that result from allocation of an executed bunched order, if the resulting security-based swaps are uncleared.

As described in the Regulation SBSR Adopting Release, to execute a bunched order, an asset manager negotiates and executes a security-based swap with a counterparty, typically a security-based swap dealer, on behalf of multiple clients. The bunched order can be executed on- or off-platform. After execution of the bunched order, the asset manager allocates a fractional amount of the aggregate notional amount of the transaction to each of several clients, thereby creating several new security-based swaps and terminating the bunched order execution.[314] By executing a bunched order, the asset manager avoids having to negotiate the client-level transactions individually, and obtains exposure for each client on the same terms (except, perhaps, for size).

In the Regulation SBSR Adopting Release, the Commission explained that Rule 901 requires a bunched order execution and the security-based swaps resulting from the allocation of the bunched order execution, if they are not cleared, to be reported like other security-based swaps.[315] The Commission further explained that Rule 902(a) requires the registered SDR that receives the report required by Rule 901 to disseminate the information enumerated in Rule 901(c) for the bunched order execution, including the full notional amount of the transaction. The Commission observed that publicly disseminating bunched order executions in this manner would allow the public to "know the full size of the bunched order execution and that this size was negotiated at a single price." [316] Existing Rule 902(c)(7) provides that a registered SDR shall not publicly disseminate any information regarding the allocation of a bunched order execution, which would include information about the security-based swaps resulting from the allocation of the initial transaction as well as the fact that the bunched order execution is terminated following this allocation.

B. Guidance on How Regulation SBSR Applies to Bunched Order Executions

In the Regulation SBSR Proposed Amendments Release, the Commission provided guidance explaining how Regulation SBSR would apply to a bunched order that is executed on a platform and will be submitted to clearing, and— if the bunched order execution is accepted for clearing—the security-based swaps that result.[317] Consistent with the principles laid out in the Regulation SBSR Adopting Release with respect to the reporting of bunched order executions that *will not* be submitted to clearing, the reporting hierarchy in existing Rule 901(a)(2)(ii) will apply to the reporting of original bunched order executions that *will be submitted to clearing.* However, the reporting of the security-based swaps resulting from the allocation of the original bunched order execution is different if a registered clearing agency is involved. Because the Commission proposed a new approach for the reporting of all clearing transactions, the Commission could not offer guidance on how Regulation SBSR applies to bunched order executions that are allocated through the clearing process until the Commission adopted final rules for the reporting of clearing transactions. Today, the Commission is adopting amendments to Rule 901 that will govern how clearing transactions must be reported, and also now is providing guidance for how bunched order executions and related allocations are to be reported when they are cleared.

1. Example 1: Off-Platform Cleared Transaction

Assume that an asset manager, acting on behalf of several advised accounts, executes a bunched order alpha with a registered security-based swap dealer. The execution does not occur on a platform, and there are no indirect counterparties on either side of the bunched order alpha. The transaction is submitted to a registered clearing agency.

a. Reporting the Bunched Order Alpha

The reporting hierarchy of existing Rule 901(a)(2)(ii) applies to the bunched order alpha because the execution does not occur on a platform and the bunched order alpha is not a clearing transaction. Under existing Rule 901(a)(2)(ii)(B), the registered security-based swap dealer is the reporting side for the bunched order alpha because its side includes the only registered security-based swap dealer. As the reporting side, the registered security-based swap dealer must report the primary and secondary trade information for the bunched order alpha to a registered SDR (the "alpha SDR") of its choice within 24 hours after the time of execution. Rule 902(a) requires the alpha SDR to publicly disseminate a transaction report of the bunched order alpha immediately upon receiving the report from the registered security-based swap dealer.[318]

When the registered security-based swap dealer submits the bunched order alpha to a registered clearing agency for clearing, Rule 901(a)(3), as adopted today, requires the registered security-based swap dealer promptly to provide the registered clearing agency with the transaction ID of the bunched order alpha and the identity of the alpha SDR. This requirement facilitates the registered clearing agency's ability to report whether or not it has accepted the bunched order alpha for clearing, as required by Rule 901(e)(1)(ii), which also is being adopted today.

b. Reporting the Security-Based Swaps Resulting From Allocation

New Rule 901(a)(2)(i) requires the registered clearing agency to report all clearing transactions that arise as a result of clearing the bunched order alpha, regardless of the workflows used to clear the bunched order alpha.[319]

If the asset manager provides allocation instructions prior to or contemporaneous with the clearing of the bunched order alpha, clearing could result in the creation of a beta (*i.e.,* the clearing transaction between the registered clearing agency and the security-based swap dealer) and a "gamma series" (*i.e.,* the gammas between the registered clearing agency and each of the client accounts selected by the asset manager to receive a portion of the initial notional amount). The beta and each security-based swap that comprises the gamma series would not

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trades-could-become-mandatory-rule.html (last visited May 25, 2016).

[314] In aggregate, the notional amount of the security-based swaps that result from the allocation is the same as the notional amount of the executed bunched order. However, as one commenter noted, "due to cross-border considerations the aggregate notional of a bunched order will not always tie out completely in reported SBSR data to the sum of the notional of its related allocations." *See* ISDA/SIFMA Letter at 28.

[315] *See* 80 FR at 14625.

[316] *Id.* at 14626.

[317] *See* 80 FR at 14753–55.

[318] Pursuant to Rule 906(a), the registered SDR also would be required to obtain any missing UICs from the counterparties.

[319] Like other clearing transactions that arise from the acceptance of a security-based swap for clearing, these security-based swaps are not subject to public dissemination. *See* Rule 902(c)(6). *See also* Rule 902(c)(7) (exempting from public dissemination any "information regarding the allocation of a security-based swap").

be treated differently under Regulation SBSR than any other clearing transactions.

If the asset manager does not provide allocation instructions until after the bunched order alpha is cleared, clearing could result in the creation of a beta (*i.e.,* the clearing transaction between the registered clearing agency and the security-based swap dealer) and an "intermediate gamma" (*i.e.,* the clearing transaction between the clearing agency and the side representing the clients of the asset manager). The beta would be the same—and would be treated the same—as any other clearing transaction, while the intermediate gamma would continue to exist until the registered clearing agency receives the allocation information, which could come from the asset manager or its clearing member and would allow for the creation of the gamma series. The registered clearing agency would report the intermediate gamma to a registered SDR of its choice. As the registered clearing agency receives the allocation information, it would terminate the intermediate gamma and create new security-based swaps as part of the gamma series. The partial terminations of the intermediate gamma would be life cycle events of the intermediate gamma that the registered clearing agency must report under existing Rule 901(e)(1)(i). Existing Rule 901(e)(2) requires the registered clearing agency to report these life cycle events to the same registered SDR to which it reported the intermediate gamma. Under new Rule 901(a)(2)(i), as adopted today, the registered clearing agency also is required to report to a registered SDR each new security-based swap comprising part of the gamma series. Because these security-based swaps arise from the termination (or partial termination) of an existing security-based swap (*i.e.,* the intermediate gamma series), existing Rule 901(d)(10) requires the registered clearing agency to link each new transaction in the gamma series to the intermediate gamma by including the transaction ID of the intermediate gamma as part of the report of each new security-based swap in the gamma series.

2. Example 2: Cleared Platform Transaction

Assume the same facts as Example 1, except that the registered security-based swap dealer and asset manager execute the bunched order alpha on a SB SEF.

a. Reporting the Bunched Order Alpha

Because the initial transaction is executed on a platform and will be submitted to clearing, the platform would have the duty under Rule 901(a)(1), as adopted today, to report the bunched order alpha to a registered SDR. To satisfy this reporting obligation, the platform must provide the information required by Rule 901(a)(1). Even if the platform does not know and thus cannot report the counterparty IDs of each account that will receive an allocation, the platform would know the identity of the execution agent who executed the bunched order alpha on behalf of its advised accounts. The platform, therefore, would report the execution agent ID of the execution agent, even though it might not know the intended counterparties of the security-based swaps that will result from the allocation.[320] Existing Rule 902(a) requires the registered SDR that receives the report of the bunched order alpha from the platform to publicly disseminate a report of the bunched order alpha. Then, pursuant to existing Rule 906(a), the registered SDR would be required to obtain any missing UICs from its participants.[321]

b. Reporting the Security-Based Swaps Resulting From Allocation

If the asset manager provides allocation instructions prior to or contemporaneous with the clearing of the bunched order alpha, clearing would (under the agency model of clearing) result in the creation of a beta (*i.e.,* the clearing transaction between the registered clearing agency and the registered security-based swap dealer) and a "gamma series" (*i.e.,* the gammas between the clearing agency and each of the asset manager's clients). The beta and each security-based swap that comprises the gamma series would be no different—and would not be treated differently under Regulation SBSR—from other clearing transactions.

If the asset manager does not provide allocation instructions until after the bunched order alpha is cleared, clearing (under the agency model) would result in the creation of a beta (between the registered clearing agency and the security-based swap dealer) and an intermediate gamma (between the registered clearing agency and the side representing the clients of the asset manager). The registered clearing agency would then be required to report the termination of the bunched order alpha and the creation of the beta and intermediate gamma, pursuant to Rules 901(e)(1)(ii) and 901(a)(2)(i), as adopted today. From this point on, the beta would be treated the same as any other clearing transaction, while the intermediate gamma would be decremented and replaced by the gamma series, as described in Example 1.

C. Comments Received

The Commission received two comments that generally supported the guidance on the proposed rules for the reporting and public dissemination of a bunched order execution that is executed on a platform and will be submitted to clearing, and the security-based swap clearing transactions that result from the allocation.[322]

One of these commenters raised concerns, however, about the application of the guidance to cross-border situations where the identity of the asset manager's clients (*i.e.,* the direct counterparties to the security-based swaps that result from the allocation) is not known at the time of bunched order execution, particularly if the Commission requires compliance with Regulation SBSR before security-based swap dealers have had the opportunity to register with the Commission as such.[323] The commenter stated that "the Commission should be aware that in advance of dealer registration determining whether a bunched order is subject to reporting under SBSR can only be based on the reporting side's understanding of the execution agent's status as a U.S. person. The U.S. person status of the funds to which the bunched order will be allocated will determine whether the allocations are subject to reporting and will have no bearing on whether the bunched order is reported."[324] The Commission shares the commenter's concern that there be clear and workable solutions for reporting transactions under Regulation SBSR even under complex cross-border scenarios. The Commission also notes that, as discussed below,[325] compliance with Regulation SBSR will be required independent of when security-based swap dealers register as such with the Commission.

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[320] *See* Rule 901(d)(1) (requiring reporting of the counterparty ID "or the execution agent ID of each counterparty, if applicable"). If the counterparties—*i.e.,* the specific accounts who will receive allocations—are not yet known, the requirement to report the execution agent ID instead of the counterparty ID would apply. Similarly, if the asset manager uses an execution agent to access the platform, the platform would report the identity of the asset manager's execution agent.

[321] One commenter stated that a registered SDRs will be unable to compel non-reporting sides to become "onboarded users" of the SDR; the commenter recommended, therefore, that the Commission require any reports, such as those required by Rule 906(a), "to only be provided to onboarded users." DTCC/ICE/CME Letter at 2. In the Regulation SBSR Adopting Release, the Commission resolved the issue of whether a non-reporting side becomes a participant of a registered SDR: It does, if the non-reporting side falls within Rule 908(b) and the transaction was reported to the registered SDR on a mandatory basis. *See* Regulation SBSR Adopting Release, 80 FR at 14645 ("The Commission recognizes that some non-reporting sides may not wish to connect directly to a registered SDR because they may not want to incur the costs of establishing a direct connection. Rule 906(a) does not prescribe the means registered SDRs must use to obtain information from non-reporting sides").

[322] *See* ISDA/SIFMA Letter at 28 (supporting "the requirement for a reporting side to report a bunched order executed off-platform, proposed rule 901(a)(1) that would require a platform to report a bunched order alpha executed on its facility, and proposed rule 901(a)(2)(i) that would require a registered clearing agency to report a cleared bunched order, if applicable, and the allocations that result from the cleared bunched order" and stating that "a bunched order should be subject to public dissemination instead of the related allocations"); ICE Trade Vault Letter at 7 (supporting inclusion of the transaction ID of the bunched order execution on each security-based swap resulting from its allocation as a "critical data element necessary to improve data quality").

[323] *See* ISDA/SIFMA Letter at 28.

In the U.S. Activity Proposal, the Commission proposed a new paragraph (a)(1)(v) to existing Rule 908(a)(1) that would subject to regulatory reporting and public dissemination any transaction in connection with a non-U.S. person's security-based swap dealing activity that is arranged, negotiated, or executed by personnel of such non-U.S. person located in a U.S. branch or office, or by personnel of an agent of such non-U.S. person located in a U.S. branch or office (an "ANE transaction"). New Rule 908(a)(1)(v)—which is being adopted today[326]—coupled with the existing provisions of Rule 908(a)(1), will further clarify how the guidance discussed above applies to various cross-border scenarios, as illustrated in the following examples:

- If the dealing entity who executes the bunched order with the asset manager/execution agent is a U.S. person, whether registered or unregistered, the bunched order execution is subject to both regulatory reporting and public dissemination because of the U.S.-person status of the dealing entity, regardless of the U.S.-person status of the asset manager/execution agent or of the funds/accounts that later receive allocations.
- If the dealing entity who executes the bunched order with the asset manager is a non-U.S. person but the bunched order execution is an ANE transaction, the bunched order execution is again subject to both regulatory reporting and public dissemination, regardless of the U.S.-person status of the asset manager/execution agent or of the funds/accounts that later receive allocations.
- If all of the funds/accounts that could be eligible to receive allocations are U.S. persons, the bunched order execution is subject to both regulatory reporting and public dissemination because of the U.S.-person status of the funds/accounts, regardless of the U.S.-person status of the dealing entity or the location of the personnel (or agent) of the dealing entity. In other words, however the asset manager/execution agent allocates the bunched order execution in this example, there is no scenario where any part of the bunched order execution could be viewed as involving a non-U.S. person. Therefore, the initial bunched order execution involving the dealing entity on one side necessarily has a U.S. person on the other side, and the initial bunched order execution is subject to both regulatory reporting and public dissemination.

The Commission acknowledges that a more complex situation arises if the bunched order execution is between an unregistered non-U.S. person who is *not* engaging in ANE activity and an asset manager/execution agent acting on behalf of funds/accounts at least some of which are non-U.S. persons. In some cases, the status of the initial bunched order execution would be resolved if the asset manager/execution agent ultimately makes allocations only to funds/accounts that are U.S. persons.[327] In other cases, however, the asset manager/execution agent[328] might make allocations to some funds/accounts that are non-U.S. persons or might not, in unusual cases, make any allocations until more than 24 hours after the time of execution of the initial bunched order. Ordinarily, the U.S.-person status of the asset manager/execution agent is not determinative of whether the bunched order execution is subject to regulatory reporting and public dissemination under Rule 908(a)(1)(i) or any other provision of Rule 908(a).[329] In this limited situation, however, the Commission believes that it would be reasonable for the sides to look to the U.S.-person status of the asset manager/execution agent to resolve whether or not the bunched order execution should be subject to regulatory reporting and public dissemination. Given that the true counterparties might be unknown or unknowable when the transaction report for the bunched order execution is due, the U.S.-person status of the asset manager/execution agent can serve as a reasonable proxy. Even if some or all of the allocation is subsequently made to funds/accounts that are not U.S. persons, it would not be inconsistent with Regulation SBSR if a regulatory report and public dissemination of the initial bunched order execution, including the full notional size, is made. Furthermore, if the asset manager/execution agent is not a U.S. person and the counterparties determine not to report the transaction on that basis, and if allocations are made to one or more funds/accounts that *are* U.S. persons, those security-based swaps resulting from the allocation would have to be reported, and the Commission would still have at least partial understanding of the overall transaction.[330] The Commission staff intends to evaluate this issue after required reporting commences.

D. Conforming Amendment to Rule 901(d)(4)

Existing Rule 901(d)(4) requires the reporting side to report, as applicable, the branch ID, broker ID, execution agent ID, trader ID, and trading desk ID of the direct counterparty on the reporting side. One commenter requested that, for bunched order executions, the reporting side be excused from this requirement because the relevant information "can only be determined upon allocation as any reported values would refer to applicable agreements with each party to an allocation and not the execution agent. SBSR should explicitly absolve platforms, clearing agencies and reporting sides from the obligation to report the information required by § 242.901(d)(4) for bunched orders." [331]

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[324] *Id.*

[325] *See infra* Section X(C).

[326] *See infra* Section IX(C).

[327] The Commission understands from discussions with market participants that allocation determinations are generally made within 24 hours after execution. In such cases, the asset manager/execution agent would know that all of the security-based swaps resulting from allocation—as well as the initial bunched order execution—are subject to regulatory reporting and public dissemination, because of the U.S.-person status of all of fund/account counterparties, before a transaction report for the initial bunched order execution is due, at least during the first interim phase of security-based swap reporting.

[328] The Commission notes that some transactions could involve more than one execution agent, and that the execution agent IDs of all execution agents of each direct counterparty would be required to be reported. *See* Regulation SBSR Adopting Release, 80 FR at 14583 ("The Commission notes that some security-based transactions may involve multiple agents").

[329] Existing Rule 908(a)(1)(i) provides that a security-based swap shall be subject to regulatory reporting and public dissemination if there "is a direct or indirect counterparty that is a U.S. person on either or both sides of the transaction." The execution agent/asset manager would not be a counterparty to the executed bunched order unless it was the primary obligor or a guarantor for the bunched order execution. *See* Rule 900(i) (defining "counterparty" for purposes of Regulation SBSR). If the asset manager/execution agent is the primary obligor or a guarantor of the security-based swap, it would be a counterparty and the outcome of the reporting hierarchy would have to reflect this fact.

[330] The commenter observed that, "due to cross-border considerations the aggregate notional of a bunched order will not always tie out completely in reported SBSR data to the sum of the notional of its related allocations." ISDA/SIFMA Letter 28. This could occur if, for example, the initial bunched order execution were reported to a registered SDR, but certain security-based swaps resulting from the allocation were not, because they did not fall within any of the prongs of Rule 908(a)(1). The Commission recognizes this possibility. However, it does not appear that this would happen to such an extent as to compromise the Commission's ability to oversee the security-based swap market.

The Commission agrees and has decided to amend Rule 901(d)(4) so that it does not apply to the initial bunched order execution, and instead applies only to the security-based swaps that result from the allocation of that bunched order execution. The relevant agreements that are to be reported pursuant to Rule 901(d)(4) are between the clients of the execution agent—*i.e.*, the funds that receive allocations—and the security-based swap dealer. The Commission believes that it is unnecessary to require these agreements to be reported twice, once with the report of the bunched order execution and once with the report of each security-based swap resulting from the allocation of the original bunched order execution. Requiring the reporting of agreement information for the bunched order execution could be challenging in instances when the clients that will receive the allocated security-based swaps are not known at the time of execution of the bunched order. Furthermore, the title and date of the relevant agreements will be included in the reports of the security-based swaps resulting from the allocation. Therefore, the Commission does not believe it is necessary to require the names and dates of the agreements to be reported with the initial bunched order execution.

VII. Reporting and Public Dissemination of Prime Brokerage Transactions

A. Background

In the Regulation SBSR Proposed Amendments Release, the Commission discussed how Regulation SBSR would apply to security-based swap transactions arising out of prime brokerage arrangements.[332] The Commission understands that, under a typical prime brokerage arrangement, a prime broker and a client enter into an agreement whereby the prime broker facilitates the client's participation in the security-based swap market by providing credit intermediation services. The prime brokerage arrangement permits the client to negotiate and agree to the terms of security-based swaps with one or more third-party "executing dealers," subject to limits and parameters specified in the prime brokerage agreement. An executing dealer would negotiate a security-based swap with the client expecting that it would face the prime broker, rather than the client, for the duration of the security-based swap. The executing dealer and/or the client would submit the transaction that they have negotiated to the prime broker. In the Regulation SBSR Proposed Amendments Release, the Commission set forth its understanding that a typical prime brokerage transaction involved three security-based swap transactions or "legs": [333]

- *Transaction 1.* The client and the executing dealer negotiate and agree to the terms of a security-based swap transaction (the "client/executing dealer transaction") and notify the prime broker of these terms. Transaction 1 is terminated upon the creation of Transaction 2 and 3, as described below.
- *Transaction 2.* If the terms of Transaction 1 are within the parameters established by the prime brokerage arrangement, the prime broker accepts the transaction and faces the executing dealer in a new security-based swap (the "prime broker/executing dealer transaction") having the same economic terms agreed to by the executing dealer and the client in Transaction 1.
- *Transaction 3.* Upon executing Transaction 2 with the executing dealer, the prime broker will enter into an offsetting security-based swap with the client (the "prime broker/client transaction").

The Commission received three comments regarding this proposed interpretation. One commenter disagreed with the Commission's view that a typical prime brokerage transaction comprises three legs, arguing that the negotiation of terms between the executing dealer and the client does not result in a transaction between the executing dealer and the client.[334] The commenter also stated that, if the prime broker did not accept the transaction, there would be no security-based swap to report (*i.e.*, there would not be a client/executing dealer transaction in the absence of acceptance by the prime broker).[335] Accordingly, the commenter requested that the Commission limit all reporting requirements arising from a prime brokerage arrangement to Transactions 2 and 3.[336] Another commenter concurred that a typical prime brokerage arrangement would result in only two legs, one between the prime broker and the executing dealer and one between the client and the prime broker.[337] The commenter expressed the view that there is not a transaction between the executing dealer and the client,[338] and that the initial negotiation between the executing dealer and the client results in a security-based swap between the executing dealer and the prime broker, with the client acting as the prime broker's agent.[339]

After considering these comments, the Commission is supplementing its views regarding the application of Regulation SBSR to prime brokerage arrangements. The Commission understands that the documentation used to structure a prime brokerage arrangement may vary. As described more fully below, the documentation may provide that the client acts as agent for the prime broker when negotiating the first leg with the executing dealer, resulting in a prime brokerage structure comprised of two legs (the prime broker/executing dealer transaction and the prime broker/client transaction). Alternatively, the documentation could provide that the negotiation between the client and the executing dealer results in a transaction between those two parties,[340] resulting in a prime brokerage structure comprised of three legs (the client/executing dealer transaction, the prime broker/executing dealer transaction, and the prime broker/client transaction). In cases where the client is acting as agent for the prime broker, the arrangement would result in the following two legs:

- *Transaction A.* The client, acting as agent for the prime broker, and the executing dealer negotiate a security-based swap transaction and notify the prime broker of its terms. If the transaction does not satisfy the parameters in the prime brokerage agreement, the prime broker may reject the transaction. If the prime broker accepts the transaction, the prime broker and the executing dealer are counterparties to the security-based swap.

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[331] ISDA/SIFMA Letter at 28–29. The commenter noted that the Commission had not proposed to require a platform to report the title and date of agreements incorporated by reference for a bunched order alpha that will be submitted to clearing. *See id.* at 28.

[332] *See* Regulation SBSR Proposed Amendments Release, 80 FR at 14755–57.

[333] *See id.* at 14755.

[334] *See* ISDA/SIFMA Letter at 20.

[335] *See id.*

[336] *See id.* at 21.

[337] *See* Memorandum from the Division of Trading and Markets regarding a November 13, 2015, meeting with representatives of SIFMA and Cleary Gottlieb Steen & Hamilton LLP (November 20, 2015), at slide 5.

[338] *See id.* at slide 11.

[339] *See id.* at slide 5.

[340] For example, the client and executing dealer could agree in advance that, in the event of rejection by the prime broker, they would preserve their contract without the involvement of the prime broker. *See* ISDA, 2005 ISDA Compensation Agreement ("ISDA Compensation Agreement") at Section 2.

- *Transaction B.* If the prime broker accepts Transaction A, the prime broker also will enter into an offsetting security-based swap with the client.

In cases where the documentation provides for a three-legged structure, the Commission is making a minor modification to Rule 902(c) to account for the situation where a registered SDR receives notice that the prime broker has rejected the transaction before the SDR has received the initial transaction report.[341] The Commission discusses below the application of the reporting and dissemination requirements as they apply to the two-legged structure and provides additional clarification in response to comments.

B. Reporting of Security-Based Swaps Resulting From Prime Brokerage Arrangements

In the Regulation SBSR Proposed Amendments Release, the Commission stated its understanding that prime brokerage arrangements involve credit intermediation offered by the prime broker, rather than a registered clearing agency; thus, prime brokerage transactions are not cleared.[342] Therefore, the application of Regulation SBSR's reporting and dissemination requirements to a prime brokerage arrangement detailed below assumes none of the security-based swaps resulting from a prime brokerage arrangement is a clearing transaction, and that none is intended to be cleared.

1. If There Are Three Legs

In the Regulation SBSR Proposed Amendments Release, the Commission set forth its proposed interpretation of the application of Regulation SBSR to the three-legged prime brokerage structure.[343] The Commission is finalizing this interpretation substantially as proposed.

Because Transaction 1 (*i.e.,* the client/executing dealer transaction) is not a clearing transaction and it is not intended to be cleared, the reporting hierarchy in existing Rule 901(a)(2)(ii) assigns the reporting duty for Transaction 1. If the prime broker accepts the transaction, the prime broker would initiate Transactions 2 and 3, which would have the effect of terminating Transaction 1. The termination would be a life cycle event of Transaction 1, and existing Rule 901(e)(2) requires the reporting side for Transaction 1 (likely the executing dealer) to report this life cycle event to the same registered SDR to which it reported Transaction 1.[344]

Transactions 2 and 3 (*i.e.,* the prime broker/executing dealer transaction and the prime broker/client transaction, respectively) also are security-based swaps that must be reported pursuant to Rule 901(a)(2)(ii). Because each of these transactions is a security-based swap that arises from the termination of another security-based swap (*i.e.,* Transaction 1), existing Rule 901(d)(10) requires the reporting of Transaction 1's transaction ID as part of the secondary trade information for each of Transaction 2 and Transaction 3.

2. If There Are Two Legs

The Commission is providing the following interpretation of the application of the reporting requirements of Regulation SBSR in cases where the documentation provides for a two-legged structure.

Existing Rule 901(a)(2)(ii) assigns the reporting duty for Transaction A (*i.e.,* the prime broker/executing dealer transaction), because Transaction A is not a clearing transaction and it is not intended to be cleared. When the client, acting as agent for the prime broker, executes Transaction A with the executing dealer, the sides (*i.e.,* the executing dealer and the prime broker) would determine the reporting side pursuant to the hierarchy set forth in existing Rule 901(a)(2)(ii). The reporting side would have up to 24 hours after the time of execution to report the applicable primary and secondary trade information of Transaction A. The client would be disclosed as the execution agent of the prime broker pursuant to Rule 901(d)(2) (if the prime broker is the reporting side) or Rule 906(a) (if the prime broker is not the reporting side).

If the prime broker accepts the transaction, the prime broker would initiate Transaction B between itself and the client. The reporting side for Transaction B also would be determined pursuant to Rule 901(a)(2)(ii). The reporting side would have up to 24 hours after the time of execution to report the applicable primary and secondary trade information of Transaction B.

C. Public Dissemination of Prime Brokerage Transactions

Existing Rule 902(a) requires public dissemination of each security-based swap, unless it falls within a category enumerated in Rule 902(c). If the documentation of the prime brokerage agreement is such that there are three security-based swaps, then each of the three is subject to public dissemination; if the documentation of the prime brokerage agreement is such that there are only two security-based swaps, both are subject to public dissemination.

If a prime broker rejects either Transaction 1 or Transaction A, the registered SDR would handle dissemination of information regarding the termination of the first transaction in the same manner as an alpha that has been rejected from clearing.[345]

One commenter reiterated an earlier request that the Commission exempt the prime broker/client leg of a prime broker transaction from public dissemination, arguing that dissemination of this transaction would provide misleading price data without providing any further transparency on costs related to prime brokerage.[346] The commenter argued that the prime broker's service fee is not relevant to security-based swap pricing.[347] In the Regulation SBSR Proposed Amendments Release, the Commission stated its preliminary belief that publicly disseminating reports of each leg of a prime brokerage transaction could provide market observers with useful information about the cost of the prime broker's credit intermediation services, because prime brokers may charge for these services by pricing the executing dealer/prime broker transaction differently than the prime broker/client transaction.[348] The Commission also noted that, with prime brokerage transactions, the only mechanism for ascertaining the charge for the credit intermediation service offered by the prime broker would be to compare the prices of Transaction 1 with the prices of any subsequent transaction.[349]

In response, the commenter noted that prime brokers might not in all cases include their fees in transaction prices and stated that, if the fees charged for prime brokerage services were useful to market observers, then such information could be more "reliably and accurately obtained by requesting it from a [prime broker].'' [350] The Commission, however, continues to believe that disseminating each leg of a prime brokerage arrangement will enhance price discovery by helping market observers to distinguish between the price of a security-based swap and the cost of credit intermediation. Market participants should not have to request information from a prime broker regarding the manner in which the cost of a prime broker's credit intermediation service might affect the price of a security-based swap when the mandate of Section 13(m)(1)(C) provides all market observers with the ability to observe the prices directly. Even if the fees charged for prime brokerage services are not always reflected in transaction prices, at least some transaction prices will include the cost of credit intermediation. Therefore, the Commission believes that none of the legs of a prime brokerage transaction should be excluded from public dissemination.

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[341] *See infra* Section VII(D).

[342] *See* 80 FR at 14755.

[343] *See id.* at 14755–57.

[344] One commenter agreed with this approach, stating that the reporting obligation should remain with the original reporting side. *See* LCH.Clearnet Letter at 11.

[345] *See infra* Section VII(D) (discussing the effect of rejection by the prime broker). *See also supra* Section III(J).

[346] *See* ISDA/SIFMA Letter at 21.

[347] *See id.*

[348] *See* 80 FR at 14756.

[349] *See id.*

In this regard, the Commission notes that Rule 907(a)(4) requires the policies and procedures of a registered SDR, in relevant part, to identify characteristics of a security-based swap that could, in the fair and reasonable estimation of the registered SDR, cause a person without knowledge of those characteristics to receive a distorted view of the market. The Commission believes that it would be difficult to comply with that requirements of the rule if a registered SDR did not identify whether individual security-based swaps are related legs of a prime brokerage transaction. If market observers are not given the ability to identify the two or three legs of a prime brokerage transaction as related, it would be difficult for market observers to avoid developing a distorted view of the market.[351]

One commenter acknowledged that a prime brokerage flag had ''potential value'' for regulatory reporting but strongly disagreed with the Commission's view that a prime brokerage flag should be publicly disseminated.[352] The commenter argued that the market for security-based swap prime brokerage services is limited, so a prime brokerage flag would have a ''high probability of compromising the anonymity'' of executing dealers and prime brokers.[353] The Commission considered similar issues in the Regulation SBSR Adopting Release relating to thinly traded security-based swaps.[354] There, the Commission declined to provide any exception to public dissemination based on the fact that only a small number of market makers were active in particular segments of the market. Here, the Commission declines to make any exception to its approach to public dissemination of prime brokerage transactions. Absent a prime brokerage flag, market observers would have no ability to know that the separate legs of a single prime brokerage transaction are related, and would incorrectly conclude that there was more market activity than in fact occurred.

Finally, one commenter noted that a prime broker/client leg might be a bunched order execution where the allocations ''are provided upfront,'' and argued that the dissemination of these multiple transactions would not enhance price discovery.[355] In the Regulation SBSR Adopting Release, the Commission provided guidance regarding how a bunched order execution must be reported and publicly disseminated (assuming that the bunched order execution is not cleared): The initial bunched order execution and any security-based swaps that result from allocating the bunched order execution are subject to regulatory reporting, while only the bunched order execution is subject to public dissemination.[356] Thus, the Commission agrees with the commenter that the security-based swaps resulting from the allocation of a prime broker/client transaction should not be publicly disseminated. However, the initial bunched order execution between the prime broker and the client is subject to public dissemination.

D. If the Prime Broker Rejects the Initial Security-Based Swap

Under either the two-leg or three-leg prime brokerage arrangements described above, the prime broker could reject the initial transaction negotiated between the client and the executing dealer. The Commission is providing guidance regarding how Regulation SBSR applies to this possibility.

The effect of the rejection by the prime broker would depend on what, if any, contractual agreement exists between the executing dealer and its client. In some cases, the client and the executing dealer could have a pre-existing agreement that would allow them to revise the security-based swap with new terms if the prime broker rejects a transaction that they have negotiated.[357] If there is such an agreement and the client and executing dealer elect to preserve a security-based swap between them, the result would have to be reported in one of two ways. If the governing documentation provides that there are only two security-based swaps that could result from the prime brokerage arrangement (*i.e.,* the initial leg is between the prime broker and the executing dealer, with the client acting as agent for the prime broker), the rejection by the prime broker would have the effect of terminating this leg, and the termination would have to be reported by the reporting side of the initial leg. The security-based swap arising between the client and the executing dealer would, because there are new counterparties, be a new security-based swap, and the reporting side for this security-based swap would be determined by the reporting hierarchy. On the other hand, if the governing documentation provides that three security-swaps would result from the prime brokerage arrangement and the client and executing dealer intend to preserve the security-based swap with different terms, the rejection by the prime broker and the amendment with the new terms would have to be reported as a life cycle event of the initial leg (presumably by executing dealer). If there is no pre-existing agreement between the client and the executing dealer that would allow for an amendment to the initially negotiated leg or such an agreement exists but the client and executing dealer elect not to keep the security-based swap in existence, the prime broker's rejection would terminate the initial leg and the reporting side of the initial leg would have to report the termination.

If rejection by the prime broker results in a termination, one of two things must occur next. If the registered SDR that received the report of the initial leg has already disseminated it, the SDR must then disseminate a follow-up report indicating that the initial security-based swap has been terminated.[358] However, situations could arise where the registered SDR had not yet disseminated a report of the initial leg when it receives notice of the termination.[359] As noted in Section III(J), *supra,* the Commission is adopting a new paragraph (c)(8) to existing Rule 902(c) providing that a registered SDR shall not publicly disseminate "[a]ny information regarding a security-based swap that has been rejected from clearing or rejected by a prime broker if the original transaction report has not yet been publicly disseminated." Therefore, if the registered SDR had not disseminated the transaction report for Transaction 1/Transaction A at the time that it receives the report of the termination of that transaction, the registered SDR would not disseminate any information regarding Transaction 1/Transaction A. Conversely, if the registered SDR had disseminated a transaction report of Transaction 1/Transaction A before receiving the termination report for that transaction, the registered SDR would disseminate a report of the termination of Transaction 1/Transaction A.

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[350] ISDA/SIFMA Letter at 21.

[351] *See supra* note 223.

[352] *See* ISDA/SIFMA Letter at 22.

[353] *Id.*

[354] *See* 80 FR at 14612.

[355] ISDA/SIFMA Letter at 21.

[356] *See* 80 FR at 14625–27. *See also* Rule 902(c)(7) (requiring a registered SDR to refrain from disseminating any information regarding the allocation of a security-based swap).

[357] *See, e.g.,* ISDA Compensation Agreement, at Section 2.

[358] *See* Rule 902(a) (requiring, in relevant part, dissemination of life cycle events when there are changes to information provided under Rule 901(c)); Rule 907(a)(3) (requiring a registered SDR, in relevant part, to have written policies and procedures for flagging transaction reports involving life cycle events).

VIII. Prohibition on Registered SDRs From Charging Fees for or Imposing Usage Restrictions on Publicly Disseminated Data

A. Background

Existing Rule 902(a) requires a registered SDR to publicly disseminate a transaction report of a security-based swap, or a life cycle event or adjustment due to a life cycle event, immediately upon receipt of information about the security-based swap, with certain exceptions noted in existing Rule 902(c). Existing Rule 900(cc) defines "publicly disseminate" to mean "to make available through the Internet or other electronic data feed that is widely accessible and in machine-readable electronic format." In the Regulation SBSR Proposed Amendments Release, the Commission stated its preliminary belief that a registered SDR should not be permitted to charge fees for the security-based swap transaction data that it is required to publicly disseminate pursuant to Regulation SBSR.[360] Accordingly, the Commission proposed new Rule 900(tt), which would define the term "widely accessible"—as used in the definition of "publicly disseminate" in existing Rule 900(cc)—to mean "widely available to users of the information on a non-fee basis." As discussed in the SBSR Proposed Amendments Release, this proposed definition of "widely accessible" would have the effect of prohibiting a registered SDR from charging fees for, or imposing usage restrictions on, the security-based swap transaction data that it is required to publicly disseminate under Regulation SBSR.[361]

In proposing this requirement, the Commission considered the statutory requirements to establish post-trade transparency in the security-based swap market, the CFTC's rules for public dissemination, and comments received in response to Regulation SBSR, as originally proposed and as re-proposed. Title VII contains numerous provisions directing the Commission to establish a regime for post-trade transparency in the security-based swap market, which are designed to give the public pricing, volume, and other relevant information about all executed security-based swap transactions.[362] In the Regulation SBSR Proposed Amendments Release, the Commission expressed the preliminary view that the statutory requirement to make this transaction information publicly available would be frustrated if registered SDRs could charge members of the public for the right to access the disseminated data.[363]

The Commission also expressed the preliminary belief that it is necessary to prohibit a registered SDR from charging users of regulatorily mandated security-based swap transaction data for public dissemination of the data to reinforce existing Rule 903(b).[364] Rule 903(b) provides that a registered SDR may disseminate information using UICs (such as product IDs or other codes, such as reference entity identifiers, that are embedded within the product IDs) or permit UICs to be used for reporting by its participants only if the information necessary to interpret such UICs is widely available on a non-fee basis. The Commission continues to be concerned that a registered SDR that wished to charge (or allow others to charge) users for the information necessary to understand these UICs—but could not, because of Rule 903(b)—might seek to do so indirectly by recharacterizing the charge as being for public dissemination. Under these circumstances, the economic benefit to the registered SDR would be the same, but the manner in which the registered SDR characterizes the fee—*i.e.,* whether as a charge to users for public dissemination or as a charge of accessing the UICs within the publicly disseminated data—would be the difference between the fee being permissible or impermissible under Rule 903(b). Accordingly, the Commission took the preliminary view that permitting a registered SDR to charge users for receiving the publicly disseminated transaction data could undermine the purposes of Rule 903(b).

The CFTC, in adopting its own rules for public dissemination of swap transactions, addressed the issue of whether a swap data repository could be allowed to charge for its publicly disseminated data. In Section 43.2 of its rules,[365] the CFTC defined "public dissemination" and "publicly disseminate" to mean "to publish and make available swap transaction and pricing data in a non-discriminatory manner, through the Internet or other electronic data feed that is widely published and in machine-readable electronic format." The CFTC also defined "widely published" to mean "to publish and make available through electronic means and *in a manner that is freely available and readily accessible to the public.*" [366] Section 43.3(d)(2) of the CFTC rules provides: "Data that is publicly disseminated . . . shall be available from an Internet Web site in a format that is freely available and readily accessible to the public." The CFTC stated that "implicit in this mandate [of public dissemination] is the requirement that the data be made available to the public at no cost," [367] and that "Section 43.3(d)(2) reflects the [CFTC]'s belief that *data must be made freely available to market participants and the public,* on a nondiscriminatory basis." [368] Although prohibiting fees on the data that swap data repositories are required to publicly disseminate, the CFTC's rules permit a swap data repository to offer, for a fee, value-added data products derived from the freely available regulatorily mandated public data and to charge fair and reasonable fees to providers of swap transaction and pricing data.[369]

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[359] For example, assume that the prime brokerage agreement provides for a three-legged structure and the executing dealer is the reporting side for the initial leg between itself and the client. However, there is no pre-existing agreement between the client and executing dealer that would allow for the terms of the initial leg to be renegotiated if the prime broker rejects the transaction. Assume further that the executing dealer does not immediately report the initial leg. *See* Rule 901(j) (generally allowing up to 24 hours after the time of execution to report a security-based swap). When the client and the executing dealer convey the results of their negotiation to the prime broker, the prime broker rejects the transaction. The executing dealer may simultaneously report to a registered SDR the terms of the initial leg and the fact that it has been rejected by the prime broker and terminated.

[360] *See* 80 FR at 14760.

[361] *See id.*

[362] *See id.* at 14759–60.

[363] *See id.* at 14760.

[364] *See id.* at 14761.

[365] 17 CFR 43.2.

[366] *Id.* (emphasis added).

[367] Real-Time Public Reporting of Swap Transaction Data (Final Rule), 77 FR 1182, 1207 (January 9, 2012).

[368] *Id.* at 1202 (emphasis added).

B. Comments Received and Final Rule

The Commission received six comments on whether registered SDRs should be permitted to charge fees or impose usage restrictions on publicly disseminated data.[370] Several commenters generally agreed with prohibiting an SDR from charging fees or imposing usage restrictions on the transaction data that it is required to publicly disseminate.[371] However, one commenter argued against imposing a prohibition against usage restrictions [372] and another requested that the Commission clarify the applicability of the prohibition.[373] After carefully considering all of the comments received, the Commission is adopting Rule 900(tt) as proposed and provides clarification, below, regarding application of the rule.

The Commission stated in the Regulation SBSR Proposed Amendments Release that the requirement that information be "widely available to users of the information on a non-fee basis" necessarily implies that a registered SDR would not be permitted to impose—or allow to be imposed—any usage restrictions on the security-based swap transaction information that it is required to publicly disseminate, including restrictions on access to or further distribution of the regulatorily mandated public security-based swap data.[374] One commenter agreed with this view [375] and another disagreed, the latter stating that a registered SDR should be able to manage redistribution of data it disseminates.[376] The commenter noted that a limitation on usage restrictions for publicly disseminated data would prevent a registered SDR from monetizing a potential revenue stream.[377] In addition, the commenter was concerned about claims related to data redistributed by others.[378] The commenter argued that a registered SDR should be permitted to impose various usage restrictions on its publicly disseminated data, such as a requirement to attribute the SDR as the source of the data, a restriction of the data to internal use, and a prohibition on redistribution of the data "without first engaging the SB SDR and agreeing on licensing terms." [379]

The Commission continues to believe that public dissemination would not satisfy the "widely available" standard in Rule 900(tt) if a registered SDR could deny access to users who do not agree to limit their use of the data in a manner directed by the registered SDR. Here, the Commission notes the asymmetric bargaining strength of the parties: A registered SDR has a monopoly position over the security-based swap transaction data that it is required to publicly disseminate, because the public has no access to that information until it is publicly disseminated. If a registered SDR could impose usage restrictions with which a user does not wish to comply, there would be no other source from which the user could freely obtain this transaction information.

The prohibition on usage restrictions would also prohibit an SDR-imposed restriction on bulk redistribution by third parties of the regulatorily mandated transaction data that the registered SDR publicly disseminates. Despite the objections of one commenter,[380] the Commission continues to believe that it could prove useful to the public for intermediaries to collect, consolidate, and redistribute the regulatorily mandated transaction data to the public. Users of the data might, instead of obtaining data directly from each of several SDRs, find it preferable to obtain the data from a single person who itself obtains the data directly from the multiple registered SDRs and consolidates it. The Commission continues to believe that allowing unencumbered redistribution best serves the policy goals of wide availability of the data and minimization of information asymmetries in the security-based swap market. Because the Commission is prohibiting registered SDRs from imposing a restriction on bulk redistribution, third parties (as well as registered SDRs themselves, as discussed below) will be able to take in the full data set and scrub, reconfigure, aggregate, analyze, repurpose, or otherwise add value to those data, and potentially sell that value-added product to others.

The Commission acknowledges the concern of the commenter who stated that "SB SDRs must be able to protect themselves from claims related to data sourced or scraped from the trade repository and redistributed by others where there are quality issues with respect to data redistributed." [381] However, a registered SDR may not, consistent with its duty to publicly disseminate under Rule 902(a) when read in connection with Rule 900(tt), require a user of the data to "agree" to any terms purporting to disclaim the SDR's responsibility for incorrect data before the user may access the regulatorily mandated public security-based swap data, as this would constitute a usage restriction. The Commission declines to make an exception for usage restrictions that are designed to limit a registered SDR's potential liability to third parties. The Commission believes that unencumbered access best serves the policy goals of wide availability of the data and minimization of information asymmetries in the security-based swap market, and that the speculative risk of SDR liability does not justify foregoing the public benefits of promoting free and unrestricted access to the security-based swap transaction data that registered SDRs are required to disseminate.

The Commission recognizes that establishing and operating a registered SDR entails various costs. The Commission does not believe, however, that prohibiting a registered SDR from charging for data that it is required to publicly disseminate will impede its ability to carry out these functions because other viable sources of revenue are available to registered SDRs. One such source may be fees imposed on persons who are required to report transactions to the SDR. Thus, the Commission believes that, with the adopted definition of "widely accessible," a registered SDR will have adequate sources of funding even if it is prohibited from charging users fees for receiving the security-based swap transaction data that the SDR is required to publicly disseminate.[382]

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[369] *See id.* at 1207.

[370] *See* Barnard I at 2; Better Markets Letter at 5; DTCC Letter at 14–15, 18–19; ICE Letter at 7; ISDA/SIFMA Letter at 29; Markit Letter at 15.

[371] *See* Barnard I at 2; ISDA/SIFMA Letter at 29; Markit Letter at 15. One commenter noted that providing data on a non-fee basis is "critical," but that the Commission's rules should also ensure equal access. *See* Better Markets Letter at 5.

[372] *See* DTCC Letter at 14–15, 18–19.

[373] *See* Markit Letter at 15.

[374] *See* Regulation SBSR Adopting Release, 80 FR at 14761.

[375] *See* ISDA/SIFMA Letter at 29.

[376] *See* DTCC Letter at 15, 19.

[377] *See id.* at 15.

[378] *See id.*

[379] *Id.* at 19. *See also id.* at 15 ("Typical restrictions on the use of data obtained from the trade repository's public dissemination might include restricting data to internal use without a license and limiting publishing, redistributing, databasing, archiving, creating derivative works, or using the data to compete with the trade repository or in a manner otherwise adverse to the trade repository. These are relatively standard clauses in data licenses"). Even if these restrictions are "standard clauses in data licenses," the Commission notes that they are not permitted under Regulation SBSR, in light of the amendments being adopted today.

[380] *See id.* ("there should be no limitations on a registered trade repository's ability to manage the redistribution of data it has previously disseminated").

[381] *Id.* at 15.

C. Other Interpretive Issues

Two commenters advocated that a registered SDR be permitted to offer value-added services related to publicly disseminated data.[383] One of these commenters stated, for example, that a registered SDR "should be permitted to commercialize aggregated SB swap data and charge fees for value-added data products that incorporate the regulatorily mandated transaction data." [384] As the Commission stated in the Regulation SBSR Proposed Amendments Release,[385] existing Rule 902(a) does not prohibit a registered SDR from creating and charging fees for a value-added data product that incorporates the regulatorily mandated transaction data, provided that the registered SDR has first satisfied its duty under Rule 902(a) to publicly disseminate the regulatorily mandated transaction data in accordance with the definition of "widely accessible." To comply with Rule 902(a), a registered SDR must publicly disseminate a transaction report of a security-based swap (assuming that the transaction does not fall within Rule 902(c)) *immediately* upon receipt of information about the security-based swap. Thus, a registered SDR would not be permitted to make its value-added product available before it publicly disseminated the regulatorily mandated transaction report because such dissemination would not comply with the requirement in Rule 902(a) that a registered SDR publicly disseminate a transaction report of a security-based swap immediately upon receipt of information about the security-based swap.

This approach is consistent with parallel CFTC rules that require regulatorily mandated data to be freely available to the public but do not prohibit a CFTC-registered swap data repository from making commercial use of such data subsequent to its public dissemination.[386] This approach also allows potential competitors in the market for value-added security-based swap data products to obtain the regulatorily mandated transaction information from registered SDRs that have a monopoly on this information until it is publicly disseminated.[387] Potential competitors to the registered SDR could be at a disadvantage if, needing the raw data for their own services, they had to purchase a value-added data product from the registered SDR or could obtain the regulatorily mandated transaction data only on a delayed basis. The Commission notes, finally, that any value-added data product offered by an SDR may be subject to certain SDR rules.[388]

A final commenter "ask[ed] the Commission to clarify that the restrictions on user fees and usage in Proposed Rule 900(tt) extends only to data that is disseminated by SDRs in a post-trade context." [389] The commenter further stated: "We note and ask the Commission to confirm that certain information contained in publicly-disseminated SBS transaction records may be proprietary and therefore subject to usage restrictions in pre-trade contexts . . . We believe this clarification is needed because in its absence, we have reason to expect some market participants to infer that because SDRs may not impose usage restrictions on information contained in a publicly-disseminated SBS record, that all such limitations on user fees and usage restrictions, *i.e.,* in pre-trade contexts, are similarly prohibited. However, we do not believe that it is the Commission's intention . . . to eliminate all user fees and usage restrictions on information contained in publicly disseminated SBS data." [390] The commenter further stated that there would not be any significant benefit to post-trade transparency from restrictions on user fees and usage in pre-trade contexts.[391]

The Commission declines to make the clarification requested by the commenter. In fact, it is the Commission's intention to eliminate all fees and usage restrictions on the information that a registered SDR is required to publicly disseminate. In the Commission's view, the commenter's distinction between "post-trade contexts"—where fees and usage restrictions could not be imposed—and "pre-trade contexts"—where, according to the commenter, they could be imposed—would be unworkable. The Commission intends for market observers to be able to take in the security-based swap transaction data that are publicly disseminated by registered SDRs on a mandatory basis and scrub, reconfigure, aggregate, analyze, repurpose, or otherwise add value to that publicly disseminated data in any manner that they see fit, without fear that doing so might subject them to liability to a third party for violating a license agreement.[392] It would be difficult if not impossible for a market observer to explain that its use of particular codes derives only from the "post-trade context" when utilization of the same codes "in the pre-trade context" might render the market observer liable to the third party who claims to own intellectual property in the code. When proposing the requirement that the information mandatorily disseminated by a registered SDR be "widely available on a non-fee basis," the Commission stated that the requirement "necessarily implies that a registered SDR would not be permitted to impose—*or allow to be imposed*—any usage restrictions on the security-based swap transaction data that it is required to publicly disseminate." [393] Thus, if a registered SDR requires or permits the use of any code or other data element where there is a reasonable threat that a third-party holder of rights in that code or in other data elements might attempt to enforce those rights against market observers, the registered SDR would not be acting consistent with Rule 903 by requiring or permitting use of that code for reporting or publicly disseminating security-based swap transaction information pursuant to Regulation SBSR. If license restrictions or any other contractual restrictions in the ''pre-trade context'' could in any way impede usage of the data in a ''post-trade context,'' then any codes or other data elements that have license restrictions may not be used under Rule 903.

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[382] One commenter, responding to the Commission's request for comment on what means exist for registered SDRs to recoup their operating costs, stated: "Non-reporting sides should be charged a minimum monthly fee for system access. This minimum charge reflects the fact that non-reporting and small volume participants tend to require equal levels of support and other resources relative to moderate and high volume participants." ICE Letter at 7. This issue is beyond the scope of this rulemaking, although the Commission notes that existing Rule 13n–4(c)(1)(i) under the Exchange Act requires an SDR to ensure that any dues, fees, or other charges imposed by the SDR are fair and reasonable and not unreasonably discriminatory.

[383] *See* DTCC Letter at 14–15, 18–19; ISDA/SIFMA Letter at 29.

[384] DTCC Letter at 14–15 (also stating that "[a]n SB SDR that is permitted to do so would likely be better equipped to bear the costs associated with operating a Commission-registered SB SDR. In turn, to the extent that such commercialization offsets the costs of operating the SDR, the costs of reporting for reporting counterparties would likely be reduced").

[385] *See* 80 FR at 14762.

[386] *See* "Real-Time Public Reporting of Swap Transaction Data" (December 20, 2011), 77 FR 1182, 1207 (January 9, 2012) (adopting rules for the public dissemination of swaps).

[387] *See infra* Section XIII(F).

[388] *See, e.g.,* Rule 13n–4(c)(1)(i) (requiring that any dues, fees, or other charges imposed by an SDR are fair and reasonable and not unreasonably discriminatory); Rule 13n–4(c)(1)(ii) (requiring an SDR to permit market participants to access specific services offered by the SDR separately); Rule 13n–4(c)(1)(iii) (requiring an SDR to establish, monitor on an ongoing basis, and enforce clearly stated objective criteria that would permit fair, open, and not unreasonably discriminatory access to services offered and data maintained by the SDR).

[389] Markit Letter at 15.

[390] *Id.* (stating that eliminating all user fees and usage restrictions in the pre-trade context "would erase much of the value of virtually all proprietary reference rates, underlier codes, prices, or indexes used in SBS transactions").

[391] *See id.*

[392] For example, a third party could take in data that are publicly disseminated by one or more registered SDRs and develop its own value-added product. The third party would be entitled to include in its own value-added product any UICs that are included in the information publicly disseminated by any registered SDR pursuant to Rule 902.

[393] Regulation SBSR Proposed Amendments Release, 80 FR at 14761 (emphasis added).

IX. Cross-Border Matters

A. Introduction

In November 2010,[394] the Commission proposed Rule 908(a) to define the scope of cross-border transactions that would be subject to Regulation SBSR's regulatory reporting and public dissemination requirements, and proposed Rule 901(a) to establish a reporting hierarchy for identifying the person that would have the duty to report the security-based swap in a variety of contexts, including cross-border contexts. In May 2013, the Commission re-proposed Rules 901 and 908 with substantial revisions as part of the Cross-Border Proposing Release.[395] The Commission adopted modified versions of re-proposed Rules 901 and 908 as part of Regulation SBSR.[396] When doing so, the Commission identified certain transactions involving non-U.S. persons that would not be addressed by Rules 901(a) and 908, as adopted in the Regulation SBSR Adopting Release, and stated its intention to seek additional comment regarding how Regulation SBSR should apply to those transactions. In April 2015, the Commission addressed those transactions in the U.S. Activity Proposal, which included proposed amendments to Rules 901(a), 908, and related rules in Regulation SBSR. These amendments would, among other things, apply Regulation SBSR's regulatory reporting and public dissemination requirements to security-based swap transactions of a non-U.S. dealing entity that are arranged, negotiated, or executed by personnel of the non-U.S. person located in a U.S. branch or office, or by the personnel of its agent located in a U.S. branch or office.[397] In addition, the Commission solicited comment on whether certain transactions of non-U.S. persons whose obligations under a security-based swap are guaranteed by a U.S. person should be exempt from the public dissemination requirement.[398]

The Commission received 16 comments regarding the U.S. Activity Proposal, of which seven discussed the proposed amendments to Regulation SBSR. In February 2016, the Commission adopted rules that require a foreign dealing entity to count against its *de minimis* threshold transactions with non-U.S. persons where the foreign dealing entity is engaging in ANE activity.[399] For the reasons discussed below, the Commission is adopting substantially as proposed the amendments to Regulation SBSR proposed in the U.S. Activity Proposal.

B. Existing Rules 901 and 908

Existing Rule 908(a)(1) requires regulatory reporting and public dissemination of any security-based swap transaction that (1) has a direct or indirect counterparty that is a U.S. person on either or both sides of the transaction, or (2) is accepted for clearing by a clearing agency having its principal place of business in the United States. Existing Rule 908(a)(2) requires regulatory reporting but not public dissemination of a transaction that has a direct or indirect counterparty that is a registered security-based swap dealer or registered major security-based swap participant on either or both sides of the transaction but does not otherwise fall within Rule 908(a)(1). In other words, Rule 908(a)(2) applies to uncleared security-based swaps of registered non-U.S. persons when there is no U.S. person on the other side.

Rule 908(b) is designed to specify the types of persons that will incur duties under Regulation SBSR. If a person does not come within any of the categories enumerated by Rule 908(b), it does not incur any duties under Regulation SBSR.[400]

Under Rule 908(a), as re-proposed in the Cross-Border Proposing Release, security-based swaps that would have fallen within the proposed definition of ''transaction conducted within the United States'' would have been among the security-based swaps subjected to both regulatory reporting and public dissemination.[401] In adopting Regulation SBSR, the Commission did not include in Rule 908(a)(1) a prong for ''transactions conducted within the United States,'' noting that commenters had expressed divergent views on this particular element of the re-proposed rule.[402] Similarly, the Commission, in the Cross-Border Proposing Release, proposed to expand Rule 908(b) to include any counterparty to a transaction conducted in the United States. However, Rule 908(b), as adopted in the Regulation SBSR Adopting Release, included only U.S. persons, registered security-based swap dealers, and registered major security-based swap participants. Thus, under the rules adopted in the Regulation SBSR Adopting Release, a non-U.S.-person security-based swap dealer or major security-based swap participant would incur an obligation under Regulation SBSR only if it were registered. The Commission noted that it anticipated soliciting additional public comment on whether regulatory reporting and/or public dissemination requirements should be extended to transactions occurring within the United States between non-U.S. persons and, if so, which non-U.S. persons should incur reporting duties under Regulation SBSR.[403] The Commission solicited comment on these questions in the U.S. Activity Proposal.[404]

While Rule 908(a) specifies what types of security-based swap transactions are subject to regulatory reporting and/or public dissemination and Rule 908(b) specifies the types of persons that will incur duties under Regulation SBSR, Rule 901(a) assigns the duty to report each individual transaction. Rule 901(a), as adopted in the Regulation SBSR Adopting Release, did not address the reporting of many types of cross-border transactions, and the Commission noted that it anticipated soliciting additional comment about how to apply Regulation SBSR, including which side should incur the reporting duty, in a security-based swap transaction between two unregistered non-U.S. persons and in a transaction between an unregistered

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[394] *See* Regulation SBSR Proposing Release, *supra* note 5.

[395] *See supra* note 5. Rule 908(a), as initially proposed, would have required regulatory reporting of any security-based swap that is ''executed in the United States or through any means of interstate commerce.'' *See* Regulation SBSR Proposing Release, 75 FR at 75287. When the Commission re-proposed Rule 908(a)(1)(i) in the Cross-Border Proposing Release, the Commission expressed concern that the language in the Regulation SBSR Proposing Release could have unduly required a security-based swap to be reported if it had only the slightest connection with the United States. *See* Cross-Border Proposing Release, 78 FR at 31061.

[396] *See* Regulation SBSR Adopting Release, 80 FR at14596–604, 14649–68.

[397] *See supra* note 87.

[398] *See* U.S. Activity Proposal, 80 FR at 27478.

[399] *See supra* note 16.

[400] *See* Regulation SBSR Adopting Release, 80 FR at 14656.

[401] Rule 900(ii), as re-proposed in the Cross-Border Proposing Release, would have defined ''transaction conducted within the United States'' to have the same meaning as in Exchange Act Rule 3a71–3(a)(5)(i), as proposed in the Cross-Border Proposing Release.

[402] *See* Regulation SBSR Adopting Release, 80 FR at 14656.

[403] *See id.*

[404] *See* 80 FR at 27489–90.

U.S. person and an unregistered non-U.S. person.[405] The U.S. Activity Proposal, among other things, proposed amendments to Rules 900, 901(a), 906, 907, and 908 of Regulation SBSR to address the regulatory reporting and public dissemination of transactions involving non-U.S. persons that were not addressed in the Regulation SBSR Adopting Release. The proposed amendments, the comments received, and final rules are discussed below.

C. Extending Regulation SBSR to All ANE Transactions

1. Description of Proposed Rule

In the U.S. Activity Proposal, the Commission proposed to add a new paragraph (a)(1)(v) to Rule 908(a)(1). Proposed Rule 908(a)(1)(v) would require any security-based swap transaction connected with a non-U.S. person's security-based swap dealing activity that is arranged, negotiated, or executed by personnel of such non-U.S. person located in a U.S. branch or office—or by personnel of its agent located in a U.S. branch or office—to be reported and publicly disseminated. This amendment would expand the scope of Regulation SBSR in two ways. First, it would require that a transaction of a foreign dealing entity be subject to both regulatory reporting and public dissemination if the non-U.S. person would be required to include the transaction in its *de minimis* threshold calculation under Rule 3a71-3(b)(1)(iii)(C) under the Exchange Act.[406] Second, the proposed rule would require public dissemination of any ANE transaction of a foreign dealing entity, even if there is no U.S. person on the other side and the transaction is not accepted for clearing by a clearing agency having its principal place of business in the United States. Under existing Rule 908(a), a transaction of a registered foreign security-based swap dealer—even if it is an ANE transaction—would be subject to regulatory reporting *but not public dissemination* if there is no U.S. person on the other side and the transaction is not accepted for clearing by a clearing agency having its principal place of business in the United States.[407]

As discussed in more detail in Section X, *infra,* the Commission in the Regulation SBSR Proposed Amendments Release did not propose to align Regulation SBSR compliance with security-based swap dealer registration. Thus, as proposed, there could have been a period of indefinite length when compliance with Regulation SBSR—including the cross-border reporting provisions thereof—could have been required when no security-based swap dealers had yet registered with the Commission. During such a period, the only way a foreign dealing entity could have been subject to duties under Regulation SBSR would have been if the foreign dealing entity were using U.S. personnel to engage in ANE activity, and the only way that a transaction involving only foreign persons would have been subject to reporting and public dissemination under Regulation SBSR would be if at least one side included a foreign dealing entity that was using U.S. personnel to engage in ANE activity with respect to that specific transaction. After security-based swap dealers register as such with the Commission, most foreign dealing entities will become subject to Regulation SBSR and assume the highest rung in the reporting hierarchy because of their registration status.

2. Discussion of Comments and Final Rule

Several commenters opposed extending Regulation SBSR's regulatory reporting and public dissemination requirements to ANE transactions.[408] One of these commenters stated, for example, that transactions between non-U.S. persons, where there is no guarantee by a U.S. person on either side, should not be required to be reported or publicly disseminated in the United States because they "lack the requisite nexus to the United States regardless of the location of conduct of the counterparties." [409] A second commenter stated that transactions that have no U.S.-person counterparty should not be publicly disseminated because they "have minimal, if any, impact on or relevance for the U.S. SBS markets even if they are arranged, negotiated or executed in the United States." [410] A third commenter argued that "[r]equiring non-registrants to publicly disseminate and report ANE transactions seems unnecessary in light of the fact that only small numbers of ANE transactions do not involve a registered SBSD or registered MSBSP and would also be unduly burdensome for non-registrants that are only engaged in *de minimis* SBS activities." [411] Two other commenters expressed concern about the costs that the proposed rule could impose on unregistered foreign dealing entities to report ANE transactions.[412] One of these commenters stated that there would be significant costs associated with reporting ANE transactions because market participants that have already designed and implemented reporting systems based on the CFTC's "status-based" approach to the scope of reporting requirements and the rules of other jurisdictions would need to modify their systems to comply with the Commission's rules.[413]

After carefully considering these comments, the Commission is adopting Rule 908(a)(1)(v) as proposed. Consistent with its territorial application of Title VII requirements,[414] the Commission believes that, when a foreign dealing entity uses U.S. personnel to arrange, negotiate, or execute a transaction in a dealing capacity, that transaction occurs at least in part within the United States and is relevant to the U.S. security-based swap market. The Commission has previously determined that ANE activity carried out by U.S. personnel warrants application of the security-based swap dealer registration requirements.[415] The Commission believes that there is sufficient "nexus" to apply Title VII's regulatory reporting and public dissemination requirements to security-based swap transactions involving a foreign dealing entity that is using U.S. personnel to engage in ANE activity with respect to a particular transaction. As the Commission has stated previously, declining to apply Title VII requirements to security-based swaps of foreign dealing entities that use U.S. personnel to engage in ANE activity would have the effect of allowing such entities "to exit the Title VII regulatory regime without exiting the U.S. market." [416] Further, as discussed in Section X, *infra,* reporting under Regulation SBSR will commence following security-based swap dealer registration. Thus, for the vast majority of transactions of foreign dealing entities falling within the scope of Rule 908(a), the reporting obligation under Regulation SBSR will arise from an entity's status as a registered security-based swap dealer, and entities that are registered as security-based swap dealers will not be required to assess whether they have engaged in ANE activity with respect to a transaction. The costs associated with the reporting of ANE transactions are discussed more fully below.

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[405] *See* Regulation SBSR Adopting Release, 80 FR at 14598.

[406] 17 CFR 240.3a71-3(b)(1)(iii)(C).

[407] Under Exchange Act Rule 3a71-1(c), 17 CFR 240. 3a71-1(c), absent a limitation by the Commission, a security-based swap dealer is deemed to be a security-based swap dealer with respect to each security-based swap that it enters into, regardless of the type, class, or category of the security-based swap or the person's activities in connection with the security-based swap. Accordingly, for purposes of this rule, any transaction that a registered security-based swap dealer arranged, negotiated, or executed using personnel located in a U.S. branch or office would be "in connection with its dealing activity" and subject to both regulatory reporting and public dissemination.

[408] *See* IIB Letter at 14-17; ISDA I at 3 (arguing generally that any security-based swap between two non-U.S. persons that is cleared outside the United States should not be subject to Regulation SBSR); SIFMA-AMG I at 5-7; SIFMA/FSR Letter at 11-14; UBS Letter at 3.

[409] SIFMA/FSR Letter at 12. In the commenter's view, public dissemination of transactions between non-U.S. persons based on U.S.-located conduct could result in the dissemination of information that is not informative or that gives a distorted view of prevailing market prices, while the regulatory reporting of these transactions would not be useful because of the minimal U.S. nexus. *See id.*

[410] *See* ISDA I at 13.

[411] UBS Letter at 3.

[412] *See* IIB Letter at 16; SIFMA/FSR Letter at 13 ("It is generally not possible to directly determine the location of counterparty conduct without substantial effort, expense and operational changes to systematically capture and process this data—burdens on market participants that will certainly outweigh the perceived regulatory benefits of obtaining transaction data for security-based swaps required to be reported as a result of U.S.-located conduct. These burdens will also fall on unregistered entities that have no reporting infrastructure and that are not well-equipped to ascertain whether they have a reporting obligation, as long as there are trades between non-U.S. persons, neither of which is a dealer").

[413] *See* IIB Letter at 16 (stating that, to modify its systems in connection with the Commission's requirements, a foreign dealing entity, including one operating below the *de minimis* threshold, "would need to install or modify a trade capture system capable of tracking, on a dynamic, trade-by-trade basis, the location of front-office personnel. The non-U.S. SBSD would then need to feed that data into its reporting system and re-code that system to account for the different rules that apply to non-U.S. SBS depending on whether they are arranged, negotiated or executed by U.S. personnel. The non-U.S. SBSD would also need to train its front office personnel in the use of this new trade capture system and develop policies, procedures, and controls to require, track, and test the proper use of that system. In addition, the non-U.S. SBSD would need to seek and obtain waivers from non-U.S. counterparties—to the extent such waivers are even permitted—with respect to privacy, blocking and secrecy laws in local jurisdictions").

a. Impact on Regulatory Reporting

The Commission notes that all security-based swaps of registered security-based swap dealers, whether U.S. or foreign, are subject to regulatory reporting under existing Rule 908(a)(2). For transactions involving foreign dealing entities that register with the Commission as security-based swap dealers, the regulatory reporting requirement stems from the involvement of the registered person, not from the presence of any ANE activity. Therefore, new Rule 908(a)(1)(v) does not subject any additional transactions involving registered security-based swap dealers to Regulation SBSR's regulatory reporting requirements.[417]

New Rule 908(a)(1)(v) extends the regulatory reporting requirements only to transactions involving an unregistered foreign dealing entity (when it engages in ANE activity) when no other condition is present that would trigger regulatory reporting (*e.g.,* there is a U.S. person or registered security-based swap dealer on the other side). Thus, Rule 908(a)(1)(v) imposes regulatory reporting requirements only to transactions in which an unregistered foreign dealing entity enters into a transaction with another unregistered foreign person.

As noted in Section II(A)(4)(d), *supra,* the Commission believes that foreign dealing entities that will register with the Commission as security-based swap dealers will be counterparties to the vast majority of security-based swaps involving foreign dealing entities engaging in U.S. activity. The Commission estimates that only a few foreign dealing entities will remain below the *de minimis* threshold and utilize U.S. personnel to engage in ANE transactions with other unregistered foreign persons. Therefore, new Rule 908(a)(1)(v) will extend Regulation SBSR's regulatory reporting requirements to only a small number of additional transactions in which an unregistered foreign dealing entity engaged in ANE activity transacts with another unregistered foreign person. In this release, the Commission estimates that only four foreign dealing entities likely will engage in ANE transactions and remain below the *de minimis* threshold, and thus be counterparties to security-based swaps that fall within Rule 908(a)(1)(v).[418]

As noted above,[419] some commenters expressed concern about the costs associated with requiring ANE transactions of unregistered foreign dealing entities to be reported, which will require an assessment of whether ANE activity is present in a particular transaction.[420] One commenter argued, for example, that regulatory reporting of these transactions "seems unnecessary in light of the fact that only small numbers of ANE transactions" would be captured by Rule 908(a)(1)(v).[421] The Commission agrees that only a small number of additional transactions will become subject to regulatory reporting because of Rule 908(a)(1)(v). However, because all ANE transactions occur at least in part within the United States, reporting these transactions to a registered SDR will enhance the Commission's ability to oversee relevant security-based swap activity within the United States as well as to evaluate market participants for compliance with specific Title VII requirements (including the requirement that a person register with the Commission as a security-based swap dealer if it exceeds the *de minimis* threshold).[422] The reporting of these additional ANE transactions also will enhance the Commission's ability to monitor for manipulative and abusive practices involving security-based swaps or transactions in related assets, such as corporate bonds.[423]

The Commission believes that certain unregistered foreign dealing entities generally will already be assessing whether they utilize U.S. personnel and, if so, whether such personnel are involved in arranging, negotiating, or executing particular security-based swaps, so that they can count such transactions against their *de minimis* thresholds. Thus, the Commission believes that new Rule 908(a)(1)(v) will impose only limited assessment costs beyond those already being incurred by unregistered foreign dealing entities.[424]

The Commission acknowledges that subjecting ANE transactions between unregistered non-U.S. persons to regulatory reporting requirements under new Rule 908(a)(1)(v) also will result in certain programmatic costs.[425] The Commission assesses those costs against the benefits of the rule to the Commission, other relevant authorities, and the market in general.[426] The Commission continues to believe that reporting of these ANE transactions to a registered SDR will enhance the Commission's ability to monitor relevant activity related to security-based swap dealing occurring within the United States as well as to monitor market participants for compliance with specific Title VII requirements (including the requirement that a person register with the Commission as a security-based swap dealer if it exceeds the *de minimis* threshold).

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[414] *See, e.g.,* U.S. Activity Adopting Release, 81 FR at 8613–17; Regulation SBSR Adopting Release, 80 FR at 14649–50; Cross-Border Adopting Release, 79 FR at 47287–88.

[415] *See* U.S. Activity Adopting Release, 81 FR at 8614 ("we do not believe that security-based swap dealing activity must create counterparty credit risk in the United States for there to be a 'nexus' sufficient to warrant security-based swap dealer registration").

[416] U.S. Activity Adopting Release, 81 FR at 8616. *See also* Cross-Border Adopting Release, 79 FR at 47288 ("Our territorial approach applying Title VII to dealing activity similarly looks to whether [relevant activities] occur with the United States, and not simply to the location of the risk").

[417] *But see infra* Section IX(C)(2)(b) (explaining that new Rule 908(a)(1)(v) subjects additional transactions involving registered security-based swap dealers to Regulation SBSR's public dissemination requirements).

[418] *See infra* note 885 and accompanying text.

[419] *See supra* notes 412–413 and accompanying text.

[420] Other comments also discussed the costs of assessing whether ANE activity is present in a transaction involving only unregistered foreign persons, but under the assumption that the Commission would require reporting compliance before requiring security-based swap dealers to register as such. *See* ISDA I at 11–13; ISDA II at 3–10; ISDA III, *passim;* ISDA/SIFMA Letter at 9–12; SIFMA–AMG I at 6–7. These comments are addressed by Section X, *infra,* where the Commission revises the proposed compliance schedule and adopts a final compliance schedule that aligns Regulation SBSR compliance with security-based swap dealer registration.

[421] UBS Letter at 3.

[422] *See* U.S. Activity Proposal, 80 FR at 27483.

[423] *See id.*

[424] *See infra* Section XII(B)(1).

b. Impact on Public Dissemination

While Rule 908(a)(1)(v) will extend Regulation SBSR's regulatory reporting requirements to additional cross-border security-based swaps—those involving unregistered foreign dealing entities when they engage in ANE transactions with other unregistered foreign persons—Rule 908(a)(1)(v) will extend Regulation SBSR's public dissemination requirements to a potentially larger number of cross-border transactions that are, under existing Regulation SBSR, subject to regulatory reporting but not public dissemination. Under existing Rule 908(a)(2), a security-based swap that does not otherwise fall within Rule 908(a)(1) shall be subject to regulatory reporting but not public dissemination if there is a registered security-based swap dealer or registered major security-based swap participant on either or both sides of the transaction. Under existing Rule 908(a)(1), a security-based swap is subject to both regulatory reporting and public dissemination only if there is a direct or indirect counterparty that is a U.S. person on either or both sides of the transaction or if the security-based swap is accepted for clearing by a clearing agency having its principal place of business in the United States. Nothing in existing Rule 908(a)(1) extends the public dissemination requirements to transactions of registered security-based swap dealers and registered major security-based swap participants based on the location of personnel who engage in relevant conduct. Thus, under existing Rule 908(a), a transaction involving only non-U.S. persons on both sides, even if one or both sides include a registered foreign security-based swap dealer, would not be subject to public dissemination. Under new Rule 908(a)(1)(v), however, the location of the personnel who engage in relevant activity on behalf of a foreign dealing entity becomes a dispositive factor for determining whether the transaction is subject to public dissemination. The Commission anticipates that a significant number of transactions between foreign registered security-based swap dealers will be with other non-U.S. persons (including other foreign registered security-based swap dealers). Under existing Rule 908(a), the overwhelming majority of these transactions would have been subject only to regulatory reporting. However, with the adoption of Rule 908(a)(1)(v), many of these transactions also will be subject to public dissemination, if there is a foreign dealing entity on either side that is engaging in ANE activity.

The Commission believes that it is appropriate to apply the public dissemination requirements to all ANE transactions, even those between two foreign counterparties where only one side is engaging in ANE activity. Transactions that are arranged, negotiated, or executed by U.S. personnel of a foreign dealing entity exist at least in part within the United States. Subjecting such transactions to public dissemination is consistent with the Commission's territorial application of Title VII requirements.[427] The Commission believes that the public dissemination of ANE transactions will increase price competition and price efficiency in the security-based swap market generally, and enable all market participants to have more comprehensive information with which to make trading and valuation determinations for security-based swaps and related and underlying assets.[428]

Thus, the Commission disagrees with the commenter who did "not believe the public dissemination of SBS between non-US Persons increases transparency to the public" [429] and another commenter who asserted that publicly disseminating such transactions between non-U.S. persons could result in the dissemination of information that is not informative or that gives a distorted view of prevailing market prices.[430] The Commission believes, to the contrary, that public dissemination of transactions between non-U.S. persons, where one or both sides are engaging in ANE activity, will be informative and will provide useful information about prevailing market prices in the U.S. security-based swap market. The fact that a foreign dealing entity uses U.S. personnel to arrange, negotiate, or execute a transaction suggests that these personnel were selected because they have familiarity with the U.S. security-based swap market, and that the instruments involved in such transactions between non-U.S. persons are typically the same or similar to instruments traded between foreign dealing entities and U.S. persons.[431] The Commission believes, therefore, that public dissemination of all ANE transactions will contribute to price discovery and price competition in the U.S. security-based swap market. The Commission further believes that—rather than providing a distorted view of prevailing market prices, as these commenters suggest—the dissemination of ANE transactions will provide a more comprehensive view of activity in the U.S. market.

Another commenter questioned the transparency benefits of publicly disseminating uncleared bilateral trades that may include bespoke terms.[432] However, as the Commission previously discussed in the Regulation SBSR Adopting Release, even bespoke transactions have price discovery value and thus should be publicly disseminated.[433] Requiring the public dissemination of all ANE transactions, whether cleared or uncleared, will increase price competition and price efficiency in the security-based swap market generally, and enable all market participants to have more comprehensive information with which to make trading and valuation determinations for security-based swaps and related and underlying assets.[434]

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[425] *See infra* notes 929 to 933 and accompanying text (discussing the programmatic costs associated with the reporting and public dissemination of ANE transactions). *See also* infra Section XIII(H) (discussing the possibility of foreign dealing entities restructuring their operations to avoid triggering reporting requirements).

[426] *See infra* Section XII(A)(4)(a) (discussing the estimated costs and benefits of new Rule 908(a)(1)(v)).

[427] *See, e.g.*, U.S. Activity Adopting Release, 81 FR at 8613–17; Regulation SBSR Adopting Release, 80 FR at 14649–50; Cross-Border Adopting Release, 79 FR at 47287–88.

[428] *See infra* Section XIII(H)(2).

[429] ISDA III at 11.

[430] *See* SIFMA/FSR Letter at 12.

[431] Various commenters noted, for example, that foreign dealing entities typically utilize U.S. personnel because such personnel have familiarity with instruments traded in the U.S. market. *See* ISDA I at 5 ("The prudent risk management of global market participants therefore requires sales and trading experts in SBS transactions to typically be located in the region of the underlying asset. Accordingly, experts in SBS products that are linked to U.S.-based underliers will usually tend to be located in the United States"); IIB Letter at 2 ("we believe that it would be desirable to foster the continued use of U.S. personnel by non-U.S. SBSDs to engage in market-facing activities. These activities are important to effective risk management by non-U.S. SBSDs in connection with SBS involving U.S. reference entities. This is because the traders with the greatest expertise and familiarity with those types of SBS are best-positioned to risk manage those positions and are typically located in the United States. . . . Centralization of pricing, hedging and risk management functions and workable integration of these functions with sales activity by non-U.S. SBSDs also helps to promote U.S. market liquidity by integrating trading interest from non-U.S. counterparties into the U.S. market"); SIFMA/FSR Letter at 6 ("For U.S.-listed products and security-based swaps based on those products, many non-U.S. dealing entities concentrate that expertise in the United States to better serve client demands").

[432] *See* IIB Letter at 15.

Another commenter expressed concerns about the market possibly front-running the hedges of a foreign dealing entity if all ANE transactions were subject to public dissemination. The Commission does not find this a persuasive argument against imposing the public dissemination requirements on all ANE transactions. The concern about public dissemination triggering adverse market impact, such as higher prices to hedge, is common to all security-based swap transactions, regardless of whether a transaction is subject to public dissemination because it involves a U.S. counterparty or because it is an ANE transaction. Therefore, as the Commission decided in the Regulation SBSR Adopting Release, all transactions will during the first phase of Regulation SBSR have up to 24 hours from the time of execution to be reported (and then immediately disseminated by a registered SDR).[435]

One commenter argued that the proposed rule would not enhance transparency in the U.S. security-based swap market because it would create incentives for non-U.S. counterparties to avoid interactions with U.S. personnel.[436] The commenter believed that the Commission's analysis of the trade-off between transparency and liquidity did not fully address the costs and benefits of applying a U.S.-personnel test to the public dissemination requirement.[437] Such fragmentation, in the commenter's view, would lead to adverse effects on effective risk management, market liquidity, and U.S. jobs. The commenter also expressed concern that the costs associated with reporting ANE transactions could lead some non-U.S. security-based swap dealers to prevent their U.S. personnel from interacting with non-U.S. counterparties, and some non-U.S. counterparties to avoid interactions with U.S. personnel.[438]

The Commission acknowledges, as this commenter suggests, that to avoid public dissemination some foreign dealing entities might prevent their U.S. personnel from interacting with non-U.S. counterparties, and some non-U.S. counterparties might avoid interactions with U.S. personnel. The Commission believes, nevertheless, that public dissemination of all ANE transactions is necessary to advance the Title VII objectives of enhancing transparency in the security-based swap market. The Commission notes that new Rule 908(a)(1)(v) extends the public dissemination requirements only to ANE transactions of foreign dealing entities with non-U.S. persons; transactions of foreign dealing entities with U.S. persons—regardless of whether they are arranged, negotiated, or executed by U.S. personnel—are already subject to existing Rule 908(a)(1)(i) by virtue of a U.S. person's involvement in the transaction. The Commission believes, therefore, that extending the public dissemination requirements to ANE transactions involving non-U.S. persons will promote a level playing field. Without Rule 908(a)(1)(v), the U.S. personnel of a foreign dealing entity might be able to offer liquidity to non-U.S. persons at lower prices than to U.S. persons, because the foreign dealing entity would not have to embed the potential costs of public dissemination into the prices offered to non-U.S. persons. By contrast, the prices offered by the foreign dealing entity to U.S. persons would likely reflect any such additional costs, to the extent that public dissemination of a particular transaction imposes costs on the counterparties.[439] While the benefit of lower prices obtained by non-U.S. persons would depend on the magnitude of the perceived costs of public dissemination, the Commission believes that it is appropriate to place the transactions of U.S. persons and non-U.S. persons on a more equal footing, so that non-U.S. persons do not have a competitive advantage over U.S. persons when engaging in security-based swap transactions that, due to the involvement of U.S. personnel of the foreign dealing entity, exist at least in part within the United States.

The commenter also argued that it would be problematic for foreign dealing entities to assess for ANE activity, which would trigger the public dissemination requirement.[440] However, such an assessment is not required unless a foreign dealing entity wishes to exclude the transaction from public dissemination because relevant activity does not occur within the United States (and there is no other basis for public dissemination under Rule 908(a)(1)). For any transaction report, the default assumption is that it is subject to public dissemination, unless the person submitting the report has appropriately flagged it as "do not disseminate." [441] A registered foreign security-based swap dealer that does not wish to assess a transaction for ANE activity could simply refrain from applying the flag and the transaction would be publicly disseminated.[442]

c. Impact of Substituted Compliance

Commenters also stated that the proposed rule could result in duplicative reporting because transactions covered by the proposed rule also would likely be reported in another jurisdiction.[443] These commenters recommended that the Commission obtain information about these transactions through information-sharing arrangements with foreign regulatory authorities, rather than establishing duplicative reporting requirements.[444] One of these commenters expressed concern that the potential for duplicative reporting could overstate trading volumes in the security-based swap market, which would not advance the G20's goal of improving transparency for derivatives.[445] Two commenters argued that foreign regulators would have a greater interest than the Commission in establishing transparency requirements for security-based swaps involving non-U.S. counterparties.[446]

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[433] *See* Regulation SBSR Adopting Release, 80 FR at 14611 ("The disseminated price [of a bespoke transaction] could, for example, still have an anchoring effect on price expectations for future negotiations in similar or related products, even in thinly-traded markets. Furthermore, even if it is difficult to compare price data across customized transactions, by disseminating reports of all bespoke transactions market observers can understand the relative number and aggregate notional amounts of transactions in bespoke products versus standardized products").

[434] *See infra* Section XIII(H)(2).

[435] *See* Rule 901(j); Appendix to Rule 901 (Reports Regarding the Establishment of Block Thresholds and Reporting Delays for Regulatory Reporting of Security-Based Swap Data); Regulation SBSR Adopting Release, 80 FR at 14616–25.

[436] *See* IIB Letter at 14. According to this commenter, a non-U.S. counterparty whose transaction was subject to public dissemination would receive a worse execution price because a dealer might widen its quotes for the transaction to counteract the risk that other market participants would front-run the dealer's hedges. The commenter suggested that, although a U.S. counterparty would have a similar incentive to avoid public dissemination of its trades, U.S. counterparties would not be in the same position as non-U.S. counterparties to avoid the application of U.S. public dissemination requirements. *See id.* at 14–15.

[437] *See id.* at 15.

[438] *See id.* at 15–16.

[439] However, to the extent that transactions of foreign dealing entities are subject to public dissemination requirements under the rules of a foreign jurisdiction, the costs of public dissemination should already be factored into the prices offered to their non-U.S. counterparties, and Rule 908(a)(1)(v) should not affect the prices that foreign dealing entities that engage in ANE transactions offer to their non-U.S. counterparties.

[440] *See* ISDA III at 11 (noting that, even if the Commission were to defer Regulation SBSR compliance until after security-based swap dealer registration, "there would still be a need to exchange ANE on transactions between Non-U.S. Persons engaged in SBS dealing activity (including between non-U.S. registered SBSD) only so the reporting side will know that it needs to send a separate message or otherwise indicate to the SDR . . . that a SBS is subject to public reporting").

[441] *See* Regulation SBSR Adopting Release, 80 FR at 14610 ("A registered SDR would not be liable for a violation of Rule 902(c) if it disseminated a report of a transaction that fell within Rule 902(c) if the reporting side for that transaction failed to appropriately flag the transaction as required by Rule 907(a)(4)").

[442] *Cf.* U.S. Activity Adopting Release, 81 FR at 8628 ("a dealer may choose to count all transactions with other non-U.S. persons towards its *de minimis* threshold, regardless of whether counting them is required, to avoid the cost of assessing the locations of personnel involved with each transaction").

The Commission acknowledges that some ANE transactions of foreign dealing entities could be subject to reporting and/or public dissemination requirements in other jurisdictions. Substituted compliance could mitigate the concerns of these commenters if the Commission issues a substituted compliance order for regulatory reporting and public dissemination of security-based swaps with respect to a particular foreign jurisdiction. In such case, a cross-border transaction involving that jurisdiction would not be subject to any direct reporting and public dissemination requirements under Regulation SBSR. A substituted compliance order would eliminate duplication with the comparable reporting and public dissemination requirements of the other jurisdiction, and concerns regarding overstated trading volumes and distortions of the market would thus not arise.[447] A person relying on substituted compliance in this manner would remain subject to the applicable Exchange Act requirements but would be complying with those requirements in an alternative fashion.

The Commission recognizes that, in practice, there will be limits to the availability of substituted compliance. For example, if the Commission were unable to make a favorable comparability determination with respect to one or more foreign jurisdiction's security-based swap reporting and dissemination requirements because they do not achieve a comparable regulatory outcome, or because the foreign trade repository or foreign authority that receives and maintains transaction reports is not subject to requirements comparable to those imposed on SDRs, the Commission would not issue a substituted compliance order with respect to that jurisdiction. The availability of substituted compliance also will depend upon the availability of supervisory and enforcement arrangements among the Commission and relevant foreign financial regulatory authorities. Although comparability assessments will focus on regulatory outcomes rather than rule-by-rule comparisons, the assessments will require inquiry regarding whether foreign regulatory requirements adequately reflect the interests and protections associated with the particular Title VII requirement. Further, only transactions in which at least one of the direct counterparties to the security-based swap is a non-U.S. person or a foreign branch are eligible for substituted compliance.

Finally, one commenter asserted that, "[w]ith respect to Non-U.S. SBS cleared outside the United States, foreign regulators have a relatively greater interest than the Commission in establishing applicable transparency requirements." [448] The Commission acknowledges that foreign regulatory authorities have a regulatory interest in security-based swaps that are cleared in their jurisdictions. However, for the reasons discussed above, the Commission also has a regulatory interest when a transaction involves ANE activity conducted by U.S. personnel of one or both sides of the transaction—even if the transaction is subsequently cleared outside the United States. Public dissemination of all ANE transactions should increase transparency and facilitate price discovery and price competition in the U.S. security-based swap market; regulatory reporting of all ANE transactions will enhance the Commission's ability to oversee the U.S. security-based swap market and the activities of U.S. personnel who are involved in arranging, negotiating, or executing such transactions. The Commission believes, therefore, that it has a compelling interest in establishing regulatory reporting and public dissemination requirements for all ANE transactions.

D. Extending Regulation SBSR to All Transactions Executed on a U.S. Platform Effected By or Through a Registered Broker-Dealer

In the U.S. Activity Proposal, the Commission proposed a new paragraph (a)(1)(iii) to Rule 908(a)(1) that would have subjected any security-based swap transaction that is executed on a platform having its principal place of business in the United States to regulatory reporting and public dissemination. The Commission also proposed a new paragraph (a)(1)(iv) to Rule 908(a)(1) that would subject any security-based swap transaction that is effected by or through a registered broker-dealer (including a registered SB SEF) to regulatory reporting and public dissemination. The Commission notes that many types of security-based swap transactions that are executed on a platform or effected by or through a registered broker-dealer are already subject to Regulation SBSR—for example, if either side includes a U.S. person [449] or a registered person,[450] or if the transaction is accepted for clearing at a clearing agency having its principal place of business in the United States.[451] Thus, proposed Rules 908(a)(1)(iii) and (iv) would have had the effect of extending regulatory reporting and public dissemination requirements to transactions occurring on a platform having its principal place of business in the United States or executed by or through a registered broker-dealer only when the counterparties consist exclusively of unregistered non-U.S. persons. In addition, proposed Rules 908(a)(1)(iii) and (iv) would have extended the public dissemination requirement to transactions involving a registered foreign security-based swap dealer that are executed on a platform or through a registered broker-dealer and not otherwise subject to public dissemination (*e.g.*, because there is a U.S. person on the other side).[452]

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[443] *See* SIFMA/FSR Letter at 12; SIFMA–AMG I at 6.

[444] *See id.*

[445] *See* SIFMA–AMG I at 2, 6. The commenter also stated that reporting the same transaction to trade repositories in the United States and the European Union could undermine the quality of publicly disseminated information because of errors caused by reporting the same transaction in multiple jurisdictions. *See id.* at 6.

[446] *See* IIB Letter at 15; SIFMA/FSR Letter at 12.

[447] The Commission further notes that, to the extent that ANE transactions involving foreign dealing entities are subject to comparable requirements for reporting and public dissemination in another foreign jurisdiction—a necessary but not sufficient condition for the Commission to issue a substituted compliance order—a foreign dealing entity would not have an incentive to avoid Regulation SBSR's public dissemination requirements by, for example, relocating its personnel, because the transaction would in any case be subject to the public dissemination requirements of the other jurisdiction. Relocating personnel or curtailing the activities of personnel who remain in the United States would be effective in avoiding public dissemination only if public dissemination requirements applied to the transaction pursuant only to Regulation SBSR.

[448] *See* IIB Letter at 15.

[449] *See* Rule 908(a)(1)(i).

[450] *See* Rule 908(a)(2).

[451] *See* Rule 908(a)(1)(ii).

Two commenters generally opposed these amendments.[453] One of these commenters stated that transactions between non-U.S. persons that have no U.S.-person guarantor—which would include transactions covered by proposed Rules 908(a)(1)(iii), (iv), and (v)—should not be subject to regulatory reporting or public dissemination in the United States because they lack the requisite nexus to the United States.[454] The other commenter expressed the view that these requirements should not apply to the security-based swaps of non-U.S. persons unless they involve a registered security-based swap dealer.[455] The commenter added that proposed Rule 908(a)(1)(iv) could provide incentives for non-U.S. counterparties to avoid transacting through registered broker-dealers, resulting in market fragmentation that would lead to adverse effects on risk management, market liquidity, and U.S. jobs.[456]

The Commission continues to believe that any transaction executed on a platform that has its principal place of business in the United States should be subject to regulatory reporting and public dissemination, even when the transaction involves two non-U.S. persons that are not engaged in dealing activity in connection with the transaction.[457] Transactions executed on a platform having its principal place of business in the United States are consummated within the United States and therefore exist, at least in part, in the United States.[458] Requiring these security-based swaps to be reported will permit the Commission and other relevant authorities to observe, in a registered SDR, all transactions executed on U.S. platforms and to carry out oversight of such transactions. With respect to public dissemination of platform-executed security-based swaps, the Commission notes that it would be inconsistent if a subset of the transactions executed on U.S. platforms—those involving unregistered non-U.S. counterparties—were not subject to public dissemination, while all other transactions executed on U.S. platforms were subject to public dissemination. Furthermore, the Commission understands that platforms typically engage in the practice of disseminating information about completed transactions to their own participants. Accordingly, the Commission believes that it would be anomalous for a platform to broadcast information about a transaction involving two non-U.S. counterparties to its participants if such transaction were not also included within Regulation SBSR's public dissemination requirements.

As the Commission previously noted in the U.S. Activity Proposal,[459] registered broker-dealers play a key role as intermediaries in the U.S. financial markets. To improve the integrity and transparency of those markets, the Commission believes that the Commission and other relevant authorities should have ready access to detailed information about the security-based swap transactions that such persons intermediate. Furthermore, the Commission believes that public dissemination of security-based swap transactions intermediated by a registered broker-dealer will provide useful information about prevailing market prices in the U.S. security-based swap market, and that regulatory reporting of such transactions will assist the Commission and other relevant authorities in overseeing the U.S. security-based swap market. Such reporting also will assist the Commission in overseeing the activities of market intermediaries that it registers.

The Commission agrees that there is some possibility that requiring the regulatory reporting and public dissemination of security-based swaps between unregistered non-U.S. persons that are intermediated by registered broker-dealers could create an incentive for those non-U.S. persons to avoid transacting through a registered broker-dealer. However, a rule that failed to capture these transactions could provide unregistered non-U.S. persons a competitive advantage over unregistered U.S. persons. The security-based swap transactions of U.S. persons effected by or through a registered broker-dealer are subject to Regulation SBSR, while the transactions between unregistered non-U.S. persons effected by or through a registered broker-dealer would not be subject to Regulation SBSR. Absent Rules 908(a)(1)(iii) and (iv), a registered broker-dealer (or platform) might be able offer its services at a lower price to non-U.S. persons than to U.S. persons, because the platform or registered broker-dealer would not have to embed the potential costs of regulatory reporting and public dissemination when pricing services offered to non-U.S. persons. By contrast, the price offered by the platform or registered broker-dealer to U.S. persons would likely reflect these additional costs. The Commission does not see a basis for permitting non-U.S. persons to enjoy this competitive advantage over U.S. persons when engaging in security-based swap transactions that, due to the involvement of a U.S. platform or registered broker-dealer, exist at least in part within the United States. Accordingly, the Commission declines to adopt the commenters' recommendation that the Commission exclude from Regulation SBSR the transactions of unregistered non-U.S. persons that are effected by or through a registered broker-dealer.

E. Public Dissemination of Covered Cross-Border Transactions

Existing Rule 908(a)(1)(i) requires regulatory reporting and public dissemination of a security-based swap if there is a direct or indirect counterparty that is a U.S. person on either or both sides of the transaction. This would include, for example, a security-based swap having, on one side, a direct counterparty who is not a U.S. person but has a U.S. guarantor, and the other side includes no counterparty that is a U.S. person, registered security-based swap dealer, or registered major security-based swap participant (a "covered cross-border transaction").[460] As discussed in the U.S. Activity Proposal, this treatment of covered cross-border transactions represented a departure from the re-proposed approach described in the Cross-Border Proposing Release, which would have excepted covered cross-border transactions from the public dissemination requirement.[461] The Commission noted, however, that it had determined to continue considering whether to except covered cross-border transactions from the public dissemination requirement and that it would solicit additional comment regarding whether such an exception would be appropriate.[462]

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[452] Under existing Rule 908(a)(2), transactions involving a registered foreign security-based swap dealer or registered foreign security-based swap market participant that do not otherwise fall within existing Rule 908(a)(1) are subject to regulatory reporting but not public dissemination.

[453] *See* IIB Letter at 15, 17; SIFMA/FSR Letter at 12–14.

[454] *See* SIFMA/FSR Letter at 12.

[455] *See* IIB Letter at 15–17.

[456] *See id.* at 16–17. As discussed in the subsection immediately above, the commenter also raised these concerns with respect to ANE transactions.

[457] *See* U.S. Activity Proposal, 80 FR at 27484.

[458] *See id.*

[459] *See* 80 FR at 27485.

[460] As in the Regulation SBSR Adopting Release, a "covered cross-border transaction" refers to a transaction that meets the description above and will not be submitted to clearing at a registered clearing agency having its principal place of business in the United States. *See* Regulation SBSR Adopting Release, 80 FR at 14653, n. 827.

[461] *See* U.S. Activity Proposal, 80 FR at 27485 (citing Cross-Border Proposing Release, 78 FR at 31062).

In the U.S. Activity Proposal, the Commission expressed its preliminary view that—in light of its determination to require all security-based swap transactions of U.S. persons, including all transactions conducted through a foreign branch, to be publicly disseminated—it did not think that it would be appropriate to exempt covered cross-border transactions from the public dissemination requirement.[463] As the Commission had previously noted in the Regulation SBSR Adopting Release,[464] a security-based swap transaction involving a U.S. person that guarantees a non-U.S. person exists, at least in part, within the United States, and the economic reality of these transactions is substantially identical to transactions entered into directly by a U.S. person (including through a foreign branch). Subjecting transactions through a foreign branch to public dissemination but excluding transactions involving a U.S.-person guarantor would treat these economically substantially identical transactions differently, and could create competitive disparities among U.S. persons, depending on how they structured their businesses. Thus, a U.S. person that engages in security-based swap transactions through a guaranteed foreign subsidiary could carry out an unlimited volume of covered cross-border transactions without being subject to the public dissemination requirement, while another U.S. person that engaged in similar transactions through a foreign branch would be subject to the public dissemination requirement.[465]

Two commenters disagreed with the Commission's proposed treatment of covered cross-border transactions.[466] One of these commenters argued that the financial risks of such transactions lie outside the United States, and that the presence of a U.S.-person guarantor would not make the pricing information relating to the transaction relevant to the U.S. market.[467] The other commenter argued not only that covered cross-border transactions should be exempt from public dissemination, but that the Commission should expand this exemption to include transactions in which both sides include a U.S.-person guarantor but neither side includes a registered security-based swap dealer or major security-based swap participant, or a U.S. person as a direct counterparty.[468] The commenter argued that, because these transactions take place outside the United States and are between two unregistered non-U.S. persons, "there is insufficient U.S. jurisdictional nexus to justify the public dissemination of the security-based swap data in the United States." [469]

The Commission disagrees with the commenter's assertions that the financial risks of covered cross-border transactions lie outside the United States and that there is insufficient U.S. jurisdictional nexus to justify the public dissemination of these transactions in the United States. As the Commission noted in the Regulation SBSR Adopting Release, a security-based swap having an indirect counterparty that is a U.S. person is economically equivalent to a security-based swap with a U.S.-person direct counterparty, and both kinds of security-based swaps exist, at least in part, within the United States.[470] The presence of a U.S. guarantor facilitates the activity of the non-U.S. person who is guaranteed and, as a result, the security-based swap activity of the non-U.S. person cannot reasonably be isolated from the U.S. person's activity in providing the guarantee.[471] The financial resources of the U.S. guarantor could be called upon to satisfy the contract if the direct counterparty fails to meet its obligations; thus, the extension of a guarantee is economically equivalent to a transaction entered into directly by the U.S. guarantor.[472] Because a U.S. guarantor might be obligated to perform under the guarantee, the Commission disagrees with the commenter's assertion that the financial risks of covered cross-border transactions lie outside the United States.

With respect to the commenter's view that covered cross-border transactions lack sufficient jurisdictional nexus to justify their public dissemination in the United States, the Commission takes the position that, under the territorial approach to Title VII described in the Regulation SBSR Adopting Release,[473] any security-based swap guaranteed by a U.S. person exists at least in part within the United States, which triggers the application of Title VII requirement for public dissemination.[474] In the Regulation SBSR Adopting Release, the Commission noted that the transparency benefits of requiring public dissemination of security-based swaps involving at least one U.S.-person direct counterparty would inure to other U.S. persons and the U.S. market generally, as other participants in the U.S. market are likely to transact in the same or related instruments.[475] In addition, the economic reality of covered cross-border transactions is substantially identical to transactions entered into directly by a U.S. person (including through a foreign branch).[476] Excluding covered cross-border transactions from public dissemination would treat these economically similar transactions differently, potentially creating competitive disparities among U.S. persons, depending on how they have structured their business.[477] To avoid such competitive disparities and to further the transparency goals of Title VII, the Commission believes that it is necessary and appropriate to require the public dissemination of covered cross-border transactions.

F. Expanding Rule 908(b)

Existing Rule 908(b) provides that, notwithstanding any other provision of Regulation SBSR, a person shall not incur any obligation under Regulation SBSR unless it is a U.S. person, a registered security-based swap dealer, or a registered major security-based swap participant. Rule 908(b) is designed to clarify the cross-border application of Regulation SBSR by specifying the types of counterparties that would and would not be subject to any duties under Regulation SBSR; if a person does not fall within any of the categories enumerated by Rule 908(b), it would not incur any duties under Regulation

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[462] *See* U.S. Activity Proposal, 80 FR at 27485.

[463] *See id.*

[464] *See* Regulation SBSR Adopting Release, 80 FR at 14653.

[465] *See* U.S. Activity Proposal, 80 FR at 27485. The Commission notes that, if the transactions of the U.S. guarantor and its foreign subsidiary are subject to regulatory reporting and public dissemination requirements in a foreign jurisdiction, such transactions could be eligible for substituted compliance if the Commission determines that the foreign requirements are comparable to those imposed by Regulation SBSR and other necessary conditions are met. *See* Rule 908(c).

[466] *See* ISDA I at 13–14; SIFMA/FSR Letter at 14.

[467] *See* ISDA I at 14.

[468] *See id.*

[469] *Id.* However, the commenter did not object to subjecting these transactions to regulatory reporting to a registered SDR. *See id.*

[470] *See* 80 FR at14653.

[471] *See id.* (citing Cross-Border Adopting Release, 79 FR at 47289).

[472] *See id.*

[473] *See* 80 FR at 14649–50.

[474] *See id.* at 14653. *See also* Cross-Border Adopting Release, 79 FR at 47289–90 ("the economic reality of the non-U.S. person's dealing activity, where the resulting transactions are guaranteed by a U.S. person, is identical, in relevant respects, to a transaction entered into directly by the U.S. guarantor").

[475] *See* 80 FR at 14651.

[476] *See* U.S. Activity Proposal, 80 FR at 27485.

[477] *See id.* However, if the transactions of a guaranteed non-U.S. person are subject to regulatory reporting and public dissemination requirements in a foreign jurisdiction and the Commission finds that the foreign requirements are comparable to those imposed by Regulation SBSR and other conditions set forth in Rule 908(c) are met, such transactions could be eligible for substituted compliance.

SBSR.[478] Rule 908(b) was designed to reduce regulatory assessment costs and provide greater legal certainty to counterparties engaging in cross-border security-based swaps.

1. Expanding Rule 908(b) To Include All Platforms and Registered Clearing Agencies

In the Regulation SBSR Proposed Amendments Release, the Commission expressed the preliminary view that all platforms and registered clearing agencies should incur the reporting duties specified in the proposed amendments to Rule 901(a),[479] even if they are not U.S. persons. Consistent with this view, the Commission proposed to expand Rule 908(b) to include any platform or registered clearing agency as among the persons that may incur duties under Regulation SBSR.[480] To the extent that a platform or registered clearing agency is a U.S. person, such entity falls within existing Rule 908(b)(1). Thus, the effect of this proposed amendment to Rule 908(b) would be to include within the rule any platform or registered clearing agency that is not a U.S. person.

Three commenters generally supported expanding Rule 908(b) to include all platforms and registered clearing agencies.[481]

The Commission is adopting the amendments to Rule 908(b) as proposed. For the reasons explained above, the Commission continues to believe that all platforms and registered clearing agencies should incur the duties specified in the amendments to Rule 901(a), even if they are not U.S. persons. Without this amendment, U.S.-person platforms and registered clearing agencies would be subject to regulatory obligations from which non-U.S.-person platforms and registered clearing agencies would be free.

2. Expanding Rule 908(b) To Include Non-U.S. Persons Engaging in ANE Transactions

In the U.S. Activity Proposal, the Commission proposed to add a new paragraph (b)(5) to Rule 908(b) to include any non-U.S. person that, in connection with such person's security-based swap dealing activity, arranges, negotiates, or executes a security-based swap using its personnel located in a U.S. branch or office, or using personnel of its agent located in a U.S. branch or office. Consistent with the proposed amendments to Rule 901(a)(2)(ii)(E) that would bring foreign dealing entities engaging in ANE transactions into the reporting hierarchy,[482] the Commission also proposed to add all non-U.S. persons engaging in ANE transactions into Rule 908(b). Because existing Rule 908(b)(2) already covers a non-U.S. person that is registered as a security-based swap dealer, the effect of proposed Rule 908(b)(5) would be to cover a non-U.S. person that engages in dealing activity in the United States but that does not meet the *de minimis* threshold and thus would not be required to register as a security-based swap dealer.[483]

The Commission received no comments that specifically addressed this proposed amendment[484] and, for the reasons discussed in the U.S. Activity Proposal, is adopting Rule 908(b)(5) as proposed. Accordingly, Rule 908(b)(5) provides that a non-U.S. person that, in connection with such person's security-based swap dealing activity, arranged, negotiated, or executed the security-based swap using its personnel[485] located in a U.S. branch or office, or using personnel of an agent located in a U.S. branch or office, may incur reporting duties under Regulation SBSR.

G. Reporting Duties of Unregistered Persons

1. Description of Proposed Rules

Existing Rule 901(a)(2)(ii) sets forth a reporting hierarchy that specifies the side that has the duty to report a security-based swap, taking into account the types of entities present on each side. Existing Rule 901(a)(2)(ii) does not assign reporting obligations for transactions involving unregistered non-U.S. persons. In the Regulation SBSR Adopting Release, the Commission stated that it anticipated soliciting further comment regarding the duty to report a security-based swap where neither side includes a registered security-based swap dealer or a registered major security-based swap participant and neither side includes a U.S. person or only one side includes a U.S. person.[486] In the U.S. Activity Proposal, the Commission proposed amendments to Rule 901(a)(2)(ii)(E) that would assign the duty to report such transactions.

As discussed in the U.S. Activity Proposal and in the Regulation SBSR Adopting Release, one commenter raised concerns about burdens that the previously re-proposed reporting hierarchy might place on U.S. persons in transactions with certain non-U.S.-person counterparties.[487] Under the previous proposal, in a transaction between a non-U.S. person and a U.S. person where neither side included a security-based swap dealer or major security-based swap participant, the U.S. person would have had the duty to report. The commenter noted that in such transactions the non-U.S.-person counterparty might be engaged in dealing activity but at levels below the security-based swap dealer *de minimis* threshold and the U.S. person might not be acting in a dealing capacity in any of its security-based swap transactions. The commenter argued that, in such cases, the non-U.S. person may be better equipped to report the transaction and, accordingly, that when two unregistered persons enter into a security-based swap, the counterparties should be permitted to select which counterparty would report, even if one counterparty is a U.S. person.[488]

The U.S. Activity Proposal included proposed Rule 901(a)(2)(ii)(E)(*2*), which the Commission proposed to address concerns arising when a non-U.S. person is engaged in ANE transactions. Under the proposed rule, in a transaction between an unregistered U.S. person and an unregistered non-U.S. person who is engaging in ANE activity, the sides would be required to select which side is the reporting side.

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[478] *See* Regulation SBSR Adopting Release, 80 FR at 14656.

[479] *See* Regulation SBSR Proposed Amendments Release, 80 FR at 14759.

[480] *See id.*

[481] *See* DTCC Letter at 18; LCH.Clearnet Letter at 11; ISDA/SIFMA Letter at 29 ("a registered platform or clearing agency should be responsible for reporting [security-based swaps] as specified in Proposed SBSR regardless of its U.S. person status").

[482] *See supra* Section IX(C).

[483] *See* U.S. Activity Proposal, 80 FR at 27486.

[484] However, two commenters noted that requiring the reporting of ANE transactions would place burdens on unregistered entities that do not have reporting infrastructure in place and would be compelled to engage third-party providers to report transactions. *See* ISDA I at 11; SIFMA/FSR Letter at 13. In addition, as discussed in Section IX(C)(2), *supra*, one commenter urged the Commission to eliminate the application of the U.S. Activity Proposal to Regulation SBSR. *See* ISDA I at 2; ISDA II at 3. These comments are addressed in Sections X(C)(7) and XII(A)(1)(d), *infra*.

[485] The Commission intends the final rule to indicate the same type of activity by personnel located in the United States as described in Section IV(C)(3) of the U.S. Activity Adopting Release, 81 FR at 8624. Moreover, for purposes of Rule 908(b)(5), the Commission interprets the term "personnel" in a manner consistent with the definition of "associated person of a security-based swap dealer" contained in Section 3(a)(70) of the Exchange Act, 15 U.S.C. 78c(a)(70), regardless of whether such non-U.S. person or such non-U.S. person's agent is itself a security-based swap dealer. *See* U.S. Activity Adopting Release, 81 FR at 8624 (discussing the Commission's interpretation of the term "personnel" for purposes of Rule 3a71–3(b)(1)(iii)(C)).

[486] *See* 80 FR at 14600, 14655.

[487] *See* IIB Letter, *passim;* Letter from Institute of International Bankers to the Commission, dated August 21, 2013.

[488] *See* U.S. Activity Proposal, 80 FR at 27486.

Also under proposed Rule 901(a)(2)(ii)(E)(*2*), if both sides are unregistered non-U.S. persons and both are engaging in ANE activity, the sides would be required to select the reporting side.

Proposed Rule 901(a)(2)(ii)(E)(*3*) was designed to address the scenario where one side is subject to Rule 908(b) and the other side is not—*i.e.,* one side includes only unregistered non-U.S. persons and that side does not engage in any ANE activity. When the other side includes an unregistered U.S. person or an unregistered non-U.S. person that *is* engaging in ANE activity, the side with the unregistered U.S. person or the unregistered non-U.S. person engaging in ANE activity would be the reporting side. The Commission preliminarily believed that the U.S. person or the non-U.S. person engaged in ANE activity generally would be more likely than the other side to have the ability to report the transaction given that it has operations in the United States.[489] The Commission also noted that, in a transaction where neither side includes a registered person, placing the duty on the side that has a presence in the United States should better enable the Commission to monitor and enforce compliance with the reporting requirement.[490]

Proposed Rule 901(a)(2)(ii)(E)(*4*) was designed to address the scenario where neither side includes a counterparty that falls within Rule 908(b)—*i.e.,* neither side includes a registered person, a U.S. person, or a non-U.S. person engaging in ANE activity—but the transaction is effected by or through a registered broker-dealer (including a registered SB SEF). In such case, the proposed rule would require the registered broker-dealer to report the transaction. The Commission preliminarily believed that the registered broker-dealer generally would be more likely than the unregistered non-U.S. counterparties (none of which are engaging in ANE activity with respect to that particular transaction) to have the ability to report the transaction given its presence in the United States and its familiarity with the Commission's regulatory requirements.[491]

2. Discussion of Comments and Final Rules

a. Transactions Where One or Both Sides Consist Only of Unregistered Persons

After careful consideration of all the comments, to which the Commission responds below, the Commission is adopting Rules 901(a)(2)(ii)(E)(*2*) and (*3*) as proposed. Rule 901(a)(2)(ii)(E)(*2*) contemplates that both sides of a security-based swap include only unregistered persons yet both sides include a person who is subject to Rule 908(b). In such case, the sides generally will have equal capacity to carry out the reporting duty; therefore, the Commission believes that it is appropriate to require them to select the reporting side. Rule 901(a)(2)(ii)(E)(*3*) contemplates that both sides include only unregistered persons and only one side includes a person who is subject to Rule 908(b). In such case, Rule 901(a)(2)(ii)(E)(*3*) assigns the reporting duty to the side that includes the person who is subject to Rule 908(b). The Commission believes that this result will help to ensure compliance with the reporting requirements of Regulation SBSR.

Two commenters expressed concerns about the expense and difficulty of determining which of these two rules to apply when one side is an unregistered foreign dealing entity who might or might not be utilizing U.S. personnel in a particular transaction.[492] These commenters warned that the burdens associated with determining whether a transaction was arranged, negotiated, or executed using U.S. personnel would unduly fall on unregistered entities that are not well-equipped to carry out a reporting obligation.[493] In raising these concerns, the commenters assumed that the Commission would require compliance with Regulation SBSR before security-based swap dealers register as such with the Commission. Requiring compliance with Regulation SBSR prior to security-based swap dealer registration would have resulted in a large number of foreign dealing entities becoming subject to reporting requirements with respect to individual transactions in which they are engaging in ANE activity before security-based swap dealer registration was required. Because these foreign dealing entities would not yet have been required to be registered as security-based swap dealers, U.S. non-dealing entities could have been required to assume greater duties in reporting such transactions and to assess on a transaction-by-transaction basis whether the other side was engaging in ANE activity.[494]

As discussed in Section X, *infra,* the Commission is adopting a revised compliance schedule that aligns Regulation SBSR compliance with the registration of security-based swap dealers. The Commission believes that foreign dealing entities that will register with the Commission as security-based swap dealers will be counterparties to the vast majority of security-based swaps involving foreign dealing entities engaging in U.S. activity.[495] Such entities will thus occupy the highest rung of the reporting hierarchy. U.S. non-dealing entities that transact with registered foreign security-based swap dealers will not have to engage in any assessment of or negotiation with the other side, because reporting duties associated with these transactions will arise from the foreign security-based swap dealers' registration status rather than any ANE activity in which they might engage.

The Commission recognizes that, even after security-based swap dealer registration occurs, there likely will be a small number of foreign dealing entities that remain below the *de minimis* threshold and thus will not have to register as security-based swap dealers. Such an unregistered foreign dealing entity—when utilizing U.S. personnel to arrange, negotiate, or execute a security-based swap—would be subject to Rule 901(a)(2)(ii)(E)(*2*) if it transacts with a U.S. person or another unregistered foreign dealing entity that is engaging in ANE activity with respect to that transaction. In such case, the sides generally will have equal capacity to carry out the reporting duty; therefore, Rule 901(a)(2)(ii)(E)(*2*) requires the sides to select the reporting side. An unregistered foreign dealing entity would be subject to Rule 901(a)(2)(ii)(E)(*3*) if it transacts with any unregistered foreign entity (including a foreign non-dealing entity or a foreign dealing entity that is not engaging in ANE activity with respect to that transaction). This approach places the duty to report directly on the only side that includes a person that is subject to Rule 908(b). The Commission estimates that only four foreign dealing entities will incur reporting obligations under new Rules 901(a)(2)(ii)(E)(*2*) and (*3*).[496]

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[489] *See id.*

[490] *See id.*

[491] *See id.*

[492] *See* ISDA I at 11–12; SIFMA/FSR Letter at 12–13.

[493] *See id.*

[494] *See* ISDA II at 6 ("The burden of exchanging and using this data *is much greater in advance of SBSD registration* since instead of relying on party level static data (such as for registration status) to apply the reporting hierarchy in SBSR in most cases, the parties may instead need to obtain and rely on transaction level party data for the U.S. Person status of the indirect counterparty or an indication of whether a non-U.S. Person with dealing activity has used U.S. personnel for ANE on each SBS") (emphasis added). The other commenter also argued that there would be significant costs and problems associated with the Commission's proposed rule. *See* SIFMA/FSR Letter at 12. The commenter recommended, however, that, "[i]f the Commission does expand the application of Regulation SBSR's regulatory reporting requirements to include transactions between two non-U.S. persons, reporting obligations triggered by U.S.-located conduct should only be triggered for registered security-based swap dealers," and acknowledged that requiring compliance after security-based swap dealers were registered "would lessen the burden imposed by the expansion of reporting requirements on unregistered entities and those parties not acting in a dealing capacity." *Id.* at 13.

[495] *See supra* Section II(A)(5), where the Commission notes that ISDA-recognized dealers (both U.S. and foreign) are involved in 74% of North American corporate single-name CDS transactions. The Commission believes that all ISDA-recognized dealers will be registered as security-based swap dealers.

Requiring additional ANE transactions of these foreign dealing entities to be reported—and requiring the foreign dealing entity and the other side to select the reporting side in a tie situation under Rule 901(a)(2)(ii)(E)(*2*) or requiring the foreign dealing entity to become the reporting side directly when it falls under Rule 901(a)(2)(ii)(E)(*3*)—will enhance the Commission's ability to oversee security-based swap dealing activity occurring with the United States and to monitor for compliance with specific Title VII requirements, including the requirement that a person register with the Commission as a security-based swap dealer if it exceeds the *de minimis* threshold. The Commission recognizes that unregistered foreign dealing entities (and other unregistered persons when they transact with unregistered foreign dealing entities) may incur costs in assessing whether these rules apply to their transactions.[497] However, requiring these ANE transactions to be publicly disseminated will further enhance the level of transparency in the U.S. security-based swap market, potentially promoting greater price efficiency by reducing implicit transaction costs.

One commenter recommended that, in a transaction between an unregistered U.S. person and an unregistered non-U.S. person engaged in ANE activity, the Commission should not require the sides to select the reporting side, but should instead place the reporting obligation on the non-U.S. person, because it is engaged in dealing activity.[498] The side engaged in dealing activity would, in the commenter's view, have a greater capacity to fulfill the reporting obligation and would likely face minimal incremental costs, because many dealing entities already have in place arrangements to report derivatives transactions.[499] The commenter expressed concern that U.S. funds "may not have the economic leverage to require their non-U.S. dealers to report" and, if an unregistered non-U.S. person did have to report, it would incur "considerable expense." [500]

The Commission does not believe that it is appropriate to modify Rule 901(a)(2)(ii)(E)(*2*) to assign the reporting duty for this transaction pair to the unregistered non-U.S. person who is engaging in ANE activity. While the Commission acknowledges the commenter's concern about the potential expense that an unregistered U.S. person could incur if it were required to report a security-based swap transaction with an unregistered foreign dealing entity, the Commission believes that it is unlikely that U.S. non-dealing entities will incur costs associated with reporting transactions themselves or costs of assessing whether an unregistered foreign dealing entity is utilizing U.S. personnel to engage in ANE activity. The foreign dealing entity's willingness to clearly indicate whether it is using U.S. personnel and to assume the reporting obligation should be a factor that a U.S. non-dealing entity likely would consider when selecting a non-U.S. person with whom to transact. If an unregistered foreign dealing entity were unable or unwilling to be selected as the reporting side (or to agree to be the reporting side only at a cost that is prohibitive to the U.S. person), the U.S. person could elect to trade with one of several registered security-based swap dealers, both U.S. and foreign, for whom reporting obligations would attach by operation of Rule 901(a)(2)(ii)(B),[501] and negotiation about which side would incur the reporting duty would not be necessary.

b. Transactions Involving a Registered Broker-Dealer

Two commenters disagreed with proposed Rule 901(a)(2)(ii)(E)(*4*),[502] which would require a registered broker-dealer (including a registered SB SEF) to report a security-based swap that it effects between two unregistered non-U.S. persons who are not engaged in ANE activity. One commenter stated that the rule would require registered broker-dealers to implement costly and robust data capturing mechanisms and requirements regarding the status of direct and indirect counterparties or the use of U.S. personnel to determine whether one side of a security-based swap is obligated to report the transaction, or whether the registered broker-dealer would have the reporting obligation.[503] Another commenter stated that the proposed rule would create a disproportionate burden on registered broker-dealers relative to the small percentage of the market represented by the transactions between non-U.S. persons that would be covered by the proposed rule.[504] Both commenters asserted that the registered broker-dealer that reports the transaction would be unable to report life cycle events for the transaction.[505] Thus, in the view of one commenter, the Commission would be unable to rely on the reported information as current and accurate.[506]

The Commission continues to believe that, to improve the integrity and transparency of the U.S. financial markets, the Commission and other relevant authorities should have ready access to transaction reports of security-based swap transactions that registered broker-dealers intermediate.[507] The Commission further believes that public dissemination of these transactions will have value to participants in the U.S. security-based swap market, who are likely to trade the same or similar products.[508] The Commission acknowledges that registered broker-dealers are required to implement policies and procedures to comply with the reporting obligation under Rule 901(a)(2)(ii)(E)(*4*), including procedures for determining the status of direct and indirect counterparties and the use of U.S. personnel to arrange, negotiate, or execute a transaction.[509] However, the Commission is not mandating specific policies and procedures, and registered broker-dealers will have flexibility in developing the appropriate processes.

The Commission further acknowledges that life cycle events for the transactions covered by Rule 901(a)(2)(ii)(E)(*4*) will not be reported. Under Rule 901(e), the reporting side for a security-based swap transaction is obligated to report life cycle event information for the transaction. Security-based swaps covered by Rule 901(a)(2)(ii)(E)(*4*) must be reported by a registered broker-dealer (including a registered SB SEF), not one of the sides. Thus, security-based swaps covered by Rule 901(a)(2)(ii)(E)(*4*) do not have a reporting side, and neither side will have an obligation to report life cycle event information for the transaction. The Commission believes, however, that the reports of these transactions, even without subsequent life cycle event reporting, will provide important information to the Commission and to market participants at the time of execution. In any event, the Commission expects that relatively few transactions will fall within Rule 901(a)(2)(ii)(E)(*4*).[510]

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[496] *See infra* Section XII(B).

[497] *See* U.S. Activity Adopting Release, 81 FR at 8626–29 (estimating assessment costs of foreign dealing entities to count transactions toward the *de minimis* thresholds under Exchange Act Rules 3a71–3(b)(1)(iii)(C) and 3a71–5(c), even if some of them do not cross the thresholds and thus are not required to register as security-based swap dealers).

[498] *See* ICI Global Letter at 7.

[499] *See id.*

[500] *Id.*

[501] Rule 901(a)(2)(ii)(B) provides that, if only one side of a security-based swap includes a registered security-based swap dealer, that side shall be the reporting side.

[502] *See* ISDA I at 14; SIFMA/FSR Letter at 14.

[503] *See* ISDA I at 14.

[504] *See* SIFMA/FSR Letter at 14.

[505] *See* ISDA I at 14; SIFMA/FSR Letter at 14.

[506] *See* ISDA I at 14.

[507] *See* U.S. Activity Proposal, 80 FR at 27485.

[508] *See id.*

[509] *See* Rule 906(c).

Finally, the Commission is modifying Rule 901(a)(2)(ii)(E)(*4*) so that the reporting requirement for a registered broker-dealer under Rule 901(a)(2)(ii)(E)(*4*) parallels the reporting requirement for a platform under final Rule 901(a)(1). The Commission believes that this change is appropriate because a registered broker-dealer, like a platform, is unlikely to know and could not without undue difficulty obtain many of the data elements contemplated by Rule 901(d). Furthermore, in many cases, a registered broker-dealer that falls within Rule 901(a)(2)(ii)(E)(*4*) also will be an SB SEF. Rule 901(a)(2)(ii)(E)(*4*), as proposed, would have required a registered broker-dealer (including a registered SB SEF) to report the information required under Rules 901(c) and (d). In contrast, final Rule 901(a)(2)(ii)(E)(*4*) requires a registered broker-dealer (including a registered SB SEF) to report only the information set forth in Rules 901(c) (except that, with respect to Rule 901(c)(5), the registered broker-dealer (including a registered SB SEF) will be required to indicate only if both direct counterparties are registered security-based swap dealers), 901(d)(9), and 901(d)(10)—in other words, the same information that a platform is required to report when it incurs a reporting duty under new Rule 901(a)(1). By eliminating the need for a registered broker-dealer to report certain data elements under Rule 901(d) that the registered broker-dealer is unlikely to know and could not learn without undue difficulty,[511] the Commission believes that the revision will help to avoid placing undue reporting burdens on registered broker-dealers (including registered SB SEFs) that incur duties as a result of new Rule 901(a)(2)(ii)(E)(*4*).

H. Conforming Amendments

1. Expanding Definition of "Participant"

Rule 900(u), as adopted in the Regulation SBSR Adopting Release, defined a "participant" of a registered SDR as "a counterparty, that meets the criteria of [Rule 908(b) of Regulation SBSR], of a security-based swap that is reported to that [registered SDR] to satisfy an obligation under [Rule 901(a) of Regulation SBSR]." In the Regulation SBSR Proposed Amendments Release, the Commission proposed an amendment to expand the definition of "participant" to include registered clearing agencies and platforms[512] and, as described above, has adopted that amendment as proposed. In the U.S. Activity Proposal, the Commission proposed to further amend the definition of "participant" to include a registered broker-dealer that is required by Rule 901(a) to report a security-based swap if it effects a transaction between unregistered non-U.S. persons that do not fall within proposed Rule 908(b)(5).[513]

The Commission received no comments regarding the proposed amendment to Rule 900(u) to include these registered broker-dealers and is adopting this amendment as proposed. The Commission continues to believe, as it stated in the U.S. Activity Proposal, that these registered broker-dealers should be participants of any registered SDR to which they are required to report security-based swap transaction information because, as SDR participants, they become subject to the requirement in Rule 901(h) to report security-based swap transaction information to a registered SDR in a format required by the registered SDR.

2. Rule 901(d)(9)

Existing Rule 901(d)(9) requires the reporting, if applicable, of the platform ID of the platform on which a security-based swap is executed. In the Regulation SBSR Adopting Release, the Commission recognized the importance of identifying the venue on which a security-based swap is executed because this information should enhance the ability of relevant authorities to conduct surveillance in the security-based swap market and understand developments in the security-based swap market generally.[514] In the U.S. Activity Proposal, the Commission proposed to amend Rule 901(d)(9) also to require the reporting, if applicable, of the broker ID of a registered broker-dealer (including a registered SB SEF) that is required by Rule 901(a)(2)(ii)(E)(*4*) to report a security-based swap effected by or through the registered broker-dealer.

The Commission received no comments regarding the proposed amendment to Rule 901(d)(9) and is adopting this amendment as proposed. The Commission continues to believe, as discussed in the U.S. Activity Proposal,[515] that being able to identify the registered broker-dealer that effects a security-based swap transaction in the manner described in Rule 901(a)(2)(ii)(E)(*4*) will enhance the Commission's understanding of the security-based swap market and improve the ability of the Commission and other relevant authorities to conduct surveillance of security-based swap market activities.

3. Limitation of Duty To Report Ultimate Parent and Affiliate Information

As discussed above, Rule 900(u), as amended herein, expands the definition of "participant" to include a registered broker-dealer that incurs the reporting obligation if it effects a transaction between two unregistered non-U.S. persons that do not fall within Rule 908(b)(5). Existing Rule 906(b) generally requires a participant of a registered SDR to provide the identity of any ultimate parent and any of its affiliates that also are participants of that registered SDR. In the Regulation SBSR Proposed Amendments Release, the Commission proposed to except platforms and registered clearing agencies from Rule 906(b)[516] and, as described above, is adopting that amendment today.[517] In the U.S. Activity Proposal, the Commission proposed to further amend Rule 906(b) to except from the duty to provide ultimate parent and affiliate information a registered broker-dealer that becomes a participant solely as a result of making a report to satisfy an obligation under Rule 901(a)(2)(ii)(E)(*4*).[518]

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[510] *See infra* note 663 (estimating that only 540 of 3,000,000 reportable events under Regulation SBSR will result from broker-dealers having to report transactions pursuant to new Rule 901(a)(2)(ii)(E)(*4*)).

[511] While the registered broker-dealer would presumably know the primary economic terms of a transaction that it is effecting, it might not know or be in a position to easily learn about the bilateral documentation that exists between the counterparties to support transactions between those counterparties. Thus, the registered broker-dealer might not be in a position to report the title and date of any master agreement, collateral agreement, margin agreement, or other agreement incorporated by reference into a security-based swap, as contemplated by Rule 901(d)(4).

[512] *See supra* Section V(A).

[513] *See* 80 FR at 27487. As in Section IX(G), *supra*, Rule 901(a)(2)(ii)(E)(*4*), as adopted herein, requires a registered broker-dealer (including a registered SB SEF) to report a security-based swap in cases where the registered broker-dealer effects a transaction between unregistered non-U.S. persons that do not fall within Rule 908(b)(5).

[514] *See* Regulation SBSR Adopting Release, 80 FR at 14589.

[515] *See* 80 FR at 27487.

[516] *See* Regulation SBSR Proposed Amendments Release, 80 FR at 14645.

[517] *See supra* Section V(D).

The Commission received no comments regarding the amendment to Rule 906(b) proposed in the U.S. Activity Proposal and is adopting this amendment as proposed. The Commission continues to believe, as it stated in the U.S. Activity Proposal,[519] that the purposes of Rule 906(b)—namely, facilitating the Commission's ability to measure derivatives exposure within the same ownership group—would not be advanced by applying the requirement to a registered broker-dealer that incurs reporting obligations solely because it effects a transaction between two unregistered non-U.S. persons that do not fall within Rule 908(b)(5). A registered broker-dealer acting solely as a broker with respect to a security-based swap is not taking a principal position in the security-based swap. To the extent that such a registered broker-dealer has an affiliate that transacts in security-based swaps, such positions could be derived from other transaction reports indicating that affiliate as a counterparty.

The Commission proposed to make a conforming amendment to Rule 907(a)(6). In the Regulation SBSR Proposed Amendments Release, the Commission proposed, and today is adopting,[520] an amendment to Rule 907(a)(6) that will require a registered SDR to have policies and procedures “[f]or periodically obtaining from each participant other than a platform or a registered clearing agency information that identifies the participant's ultimate parent(s) and any participant(s) with which the participant is affiliated, using ultimate parent IDs and counterparty IDs.”[521] In the U.S. Activity Proposal, the Commission proposed to further amend Rule 907(a)(6) to except a registered broker-dealer that incurs reporting obligations solely because it effects a transaction between two unregistered non-U.S. persons that do not fall within Rule 908(b)(5).[522] The Commission received no comments regarding the proposed amendment to Rule 907(a)(6) and is adopting the amendment as proposed. Because such a broker-dealer has no duty under Rule 906(b), as amended, to provide such information to a registered SDR, no purpose would be served by requiring the registered SDR to have policies and procedures for obtaining this information from the broker-dealer.

I. Availability of Substituted Compliance

Existing Rule 908(c)(1) describes the possibility of substituted compliance with respect to regulatory reporting and public dissemination of security-based swap transactions. Substituted compliance could be available for transactions that will become subject to Regulation SBSR because of the amendments to Rule 908 being adopted today. Under Rule 908(c)(1), a security-based swap is eligible for substituted compliance with respect to regulatory reporting and public dissemination if at least one of the direct counterparties to the security-based swap is either a non-U.S. person or a foreign branch. As discussed in the U.S. Activity Proposal, existing Rule 908(c) does not condition substituted compliance eligibility on where a particular transaction was arranged, negotiated, or executed.[523] Thus, Rule 908(c) permits a security-based swap between a U.S. person and the New York branch of a foreign bank (*i.e.,* a non-U.S. person utilizing U.S.-located personnel) potentially to be eligible for substituted compliance, if the transaction is also subject to the rules of a foreign jurisdiction that is the subject of a Commission substituted compliance order.

The rules adopted today, among other things, subject to regulatory reporting and public dissemination both ANE transactions and security-based swaps executed on a U.S. platform or effected by a registered broker-dealer. The Commission did not propose, and is not adopting, any amendment to Rule 908(c) that would limit the availability of substituted compliance for such transactions based on the location of the relevant activity. Thus, a transaction that is required to be reported and publicly disseminated because it is an ANE transaction, or because it is executed on a U.S. platform or effected by or through a registered broker-dealer, could be eligible for substituted compliance if the Commission issues a substituted compliance order with respect to regulatory reporting and public dissemination of security-based swaps applying to that jurisdiction. This approach is consistent with the Commission's decision when adopting Rule 908(c) that certain transactions involving U.S.-person counterparties could be eligible for substituted compliance (*i.e.,* when the transaction is through the foreign branch of the U.S. person) even if the non-U.S.-person counterparty has engaged in dealing activity in connection with the transaction in the United States. One commenter who generally opposed the regulatory reporting and public dissemination requirements proposed in the U.S. Activity Proposal specifically supported the Commission's approach to substituted compliance.[524]

Finally, several commenters expressed the view that reporting pursuant to Regulation SBSR should not begin until the Commission has made substituted compliance determinations.[525] As discussed in Section X(C)(5), *infra,* the Commission does not believe that it is necessary or appropriate to defer compliance with Regulation SBSR until after the Commission makes one or more substituted compliance determinations.[526]

X. Compliance Schedule for Regulation SBSR

In the Regulation SBSR Adopting Release, the Commission established a compliance date only for Rules 900, 907, and 909 of Regulation SBSR.[527] In the Regulation SBSR Proposed Amendments Release, the Commission proposed a new compliance schedule for Rules 901, 902, 903, 904, 905, 906, and 908 of Regulation SBSR.[528] The

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[518] However, a registered broker-dealer would have to comply with Rule 906(b) if it became a participant of a registered SDR for another reason—*e.g.,* the broker-dealer is a U.S. person and is a counterparty to a security-based swap that is reported to the registered SDR on a mandatory basis.

[519] *See* 80 FR at 27488.

[520] *See supra* Section V(D).

[521] Once a participant reports parent and affiliate information to a registered SDR, Rule 906(b) requires the participant to “promptly notify the registered [SDR] of any changes” to its parent and affiliate information.

[522] *See* U.S. Activity Proposal, 80 FR at 27488.

[523] *See id.*

[524] *See* IIB Letter at 15, 17.

[525] *See* ISDA I at 15 (stating that the reporting of security-based swap transactions of non-U.S. registered persons with other non-U.S. persons should not be required until a cross-border analysis has been understand and substituted compliance determinations have been made); ISDA/SIFMA Letter at 19 (stating that the security-based swap transactions of non-U.S. registered security-based swap dealers should not be required until the Commission has analyzed reporting regimes in other jurisdictions and made relevant substituted compliance determinations, consistent with the CFTC's determination to provide time-limited exemptive relief for swaps between non-U.S. swap dealers and non-U.S. persons while the CFTC analyzes the cross-border implications of reporting); SIFMA/FSR Letter at 15 (asking the Commission to defer compliance with Regulation SBSR “until [the Commission] has the opportunity to make comparability determinations for key non-U.S. jurisdictions, including Australia, Canada, the European Union, Japan and Switzerland,” and stating that “Requiring the changes to systems, personnel and trade flows necessary to comply with [the U.S. Activity Proposal] only to later be granted substituted compliance would impose significant and unnecessary burdens for negligible short-term benefits”).

[526] *See also infra* Section XII(A)(7).

[527] *See* 80 FR at 14564. The compliance date for Rules 900, 907, and 909 was also the effective date of Regulation SBSR: May 18, 2015.

[528] *See* 80 FR at 14762–70.

Commission believed that proposing a new compliance schedule was necessary in light of the fact that industry infrastructure and capabilities had changed since the initial proposal,[529] particularly because the CFTC regime for swap data reporting and dissemination had become operational. The Commission received 13 comments that discuss the proposed compliance schedule. After careful consideration of these comments, the Commission is adopting a revised compliance schedule, as described in detail below.

A. Proposed Compliance Schedule

The Commission proposed the following phased-in compliance schedule for Rules 901, 902, 903, 904, 905, 906, and 908 of Regulation SBSR.[530] First, the Commission proposed a Compliance Date 1 to be the date six months after the first registered SDR that can accept reports of security-based swaps in a particular asset class commences operations as a registered SDR. On proposed Compliance Date 1, persons with a duty to report security-based swaps under Regulation SBSR would have been required to report all newly executed security-based swaps in that asset class to a registered SDR. After proposed Compliance Date 1, persons with a duty to report security-based swaps also would have a duty to report any life cycle events of any security-based swaps that previously had been required to be reported. In addition, under the proposed compliance schedule, transitional and pre-enactment security-based swaps would also have been reported, to the extent information was available, to a registered SDR that accepts reports of security-based swap transactions in the relevant asset class by proposed Compliance Date 1.[531] The Commission also proposed a Compliance Date 2, which would have been nine months after the first registered SDR that can accept security-based swaps in a particular asset class commences operations as a registered SDR (*i.e.*, three months after proposed Compliance Date 1). On proposed Compliance Date 2, each registered SDR in that asset class would have had to comply with Rules 902 (regarding public dissemination), 904(d) (requiring dissemination of transaction reports held in queue during normal or special closing hours), and 905 (with respect to public dissemination of corrected transaction reports) for all security-based swaps in that asset class—except for covered cross-border transactions.[532]

The proposed compliance schedule with respect to security-based swaps in a particular asset class was tied to the commencement of operations of a registered SDR that can accept reports of security-based swaps in that asset class. In the Regulation SBSR Proposed Amendments Release, the Commission noted that both registered SDRs and persons with a duty to report would need time to make preparations related to the reporting of security-based swaps.[533] The proposed compliance schedule was not, however, linked to security-based swap dealer registration.

B. General Summary of Comments Received

Commenters expressed a variety of concerns with the proposed compliance schedule. Most of the comments that addressed the proposed compliance schedule urged the Commission to delay implementation of Regulation SBSR until after security-based swap dealers are registered as such with the Commission.[534] Commenters generally expressed concerns with the costs and burdens of implementing Regulation SBSR ahead of the SBS entities registration compliance date, particularly the costs for buy-side U.S. persons. Commenters also expressed concerns that allowing the SBS entities registration compliance date to follow the implementation of Regulation SBSR would complicate reporting in the interim period between the two dates. Many of these commenters also expressed concerns that the reporting of historical security-based swaps would be significantly more difficult if compliance for reporting were required before the SBS entities registration compliance date.[535]

Some commenters expressed concerns about basing the compliance schedule for an asset class on the registration of the first SDR that can accept security-based swaps in that asset class, which, they argued, could confer an unfair "first mover" advantage.[536] One of these commenters recommended that the Commission consider a compliance schedule that would base the first compliance date on the registration of a "critical mass" of SDRs.[537]

Other commenters expressed concern about how the reporting requirements contained in Regulation SBSR could be implemented before the Commission finalizes its rules regarding SB SEFs.[538] Some commenters urged the Commission to defer compliance with Regulation SBSR until the Commission makes one or more substituted compliance determinations with respect to regulatory reporting and public dissemination of security-based swap transactions in foreign jurisdictions.[539] Still others suggested that the Commission defer compliance with the requirement to report certain UICs until international standards for UICs are developed.[540] Several commenters expressed concerns that differences between Regulation SBSR and the parallel CFTC rules would present significant implementation challenges for SDRs and market participants that seek to operate in both the swap and security-based swap markets.[541] Various commenters generally urged the Commission to provide adequate time for the development and implementation of the required compliance systems and procedures.[542]

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[529] *See* 80 FR at 14762. *See also* Regulation SBSR Proposing Release, 75 FR at 75242–45 (proposing Rules 910 and 911 to explain compliance dates and related implementation requirements).

[530] *See* Regulation SBSR Proposed Amendments Release, 80 FR at 14762–70.

[531] A transitional security-based swap is "a security-based swap executed on or after July 21, 2010, and before the first date on which trade-by-trade reporting of security-based swaps in that asset class to a registered security-based swap data repository is required pursuant to §§ 242.900 through 242.909." *See* Rule 900(nn). A pre-enactment security-based swap is "any security-based swap executed before July 21, 2010 (the date of enactment of the Dodd-Frank Act (Pub. L. 111–203, H.R. 4173)), the terms of which had not expired as of that date." *See* Rule 900(y).

[532] A covered cross-border transaction is a security-based swap that has, on one side, a direct counterparty who is not a U.S. person but has a U.S. guarantor, and on the other side has no counterparty that is a U.S. person, registered security-based swap dealer, or registered major security-based swap participant. Such a transaction will not be submitted to clearing at a registered clearing agency having its principal place of business in the United States. *See* Regulation SBSR Adopting Release, 80 FR at 14653, n. 827.

[533] *See* 80 FR at 14763.

[534] *See* IIB Letter at 17; ISDA I at 4, 11–13; ISDA II at 1–14; ISDA III at 1–12; SIFMA–AMG II at 6–7; UBS Letter at 2; WMBAA Letter at 5–6.

[535] *See* ISDA/SIFMA Letter at 16–17; ISDA II at 10; ISDA III at 2, 4.

[536] *See* WMBAA Letter at 6; DTCC Letter at 12; SIFMA Letter at 17; DTCC/ICE/CME Letter at 4–5; ISDA/SIFMA Letter at 18.

[537] WMBAA Letter at 5.

[538] *See* WMBAA Letter at 5–6; ISDA/SIFMA Letter at 3.

[539] *See* ISDA/SIFMA Letter at 19–20; SIFMA/FSR Letter at 15; IIB Letter at 19.

[540] *See* ISDA/SIFMA Letter at 3, 12; DTCC/ICE/CME Letter at 3–4; Financial InterGroup Letter at 4; DTCC Letter at 2–3.

[541] *See* DTCC Letter at 21 ("SB SDR applicants would be forced to expand their operations considerably, particularly to address the confirmation functions and code issuance responsibilities"); ICE Letter at 8; ISDA/SIFMA Letter at 8 ("reporting sides and market infrastructure providers will need to engage in significant builds and development of new industry standards in order to comply"); WMBAA Letter at 5.

[542] *See* Financial InterGroup Letter at 1; WMBAA Letter at 5–6; ISDA/SIFMA Letter at 8–18.

These comments and the Commission's responses thereto are discussed in more detail below. The Commission is adopting the primary features of the proposed compliance schedule but is making several revisions in response to comments. Most notably, as described below, the Commission had decided to align the compliance dates for Regulation SBSR with the SBS entities registration compliance date.

C. Compliance Date 1

Under the compliance schedule adopted today, with respect to newly executed security-based swaps in a particular asset class, Compliance Date 1 for Rule 901 of Regulation SBSR is the first Monday that is the later of: (1) Six months after the date on which the first SDR that can accept transaction reports in that asset class registers with the Commission; or (2) one month after the SBS entities registration compliance date. Every security-based swap in that asset class that is executed on or after Compliance Date 1 must be reported in accordance with Rule 901.[543]

Furthermore, Rule 901—which imposes reporting duties on specified persons beginning on Compliance Date 1—must be read in connection with Rules 908(a) and 908(b) on Compliance Date 1. Thus, for example, a non-U.S. person who falls within one of the categories set forth in Rule 908(b) could, under Rule 901(a), be required on Compliance Date 1 to report a cross-border security-based swap if the security-based swap falls within one of the categories set forth in Rule 908(a). Also, when persons with reporting duties begin mandatory reporting on Compliance Date 1, they must do so in a manner consistent with Rule 903, which addresses the use of coded information in the reporting of security-based swaps.

Beginning on Compliance Date 1, registered SDRs must comply with Rule 904, which addresses the operating hours of registered SDRs, except for Rule 904(d).[544]

Also beginning on Compliance Date 1, counterparties and registered SDRs must comply with Rule 905 regarding the correction of errors in previously reported information about security-based swaps in that asset class, except that the registered SDR will not yet be subject to the requirement in Rule 905(b)(2) to publicly disseminate any corrected transaction reports (because it will not yet be required to publicly disseminate a report of the initial transaction). Furthermore, beginning on Compliance Date 1, each registered SDR must comply with the requirement in Rule 906(a) to provide to each participant of that SDR a report of any missing UICs, and any participant receiving such a report must comply with the requirement in Rule 906(a) to provide the missing UICs to the registered SDR. By Compliance Date 1, participants enumerated in Rule 906(c) must establish the policies and procedures required by Rule 906(c).

1. Compliance With Regulation SBSR Follows Security-Based Swap Dealer Registration

Several commenters strongly urged the Commission to defer Compliance Date 1 until security-based swap dealers must register with the Commission.[545] These commenters correctly observed that, during any interim period beginning on the date that the Commission requires reporting of newly executed security-based swaps in a particular asset class but before the SBS entities registration compliance date (the "Interim Period"), there would be no registered security-based swap dealers or registered major security-based swap participants to occupy the highest rungs of the reporting hierarchy in Rule 901(a)(2)(ii). Therefore, during any such Interim Period, any security-based swap covered by the reporting hierarchy would either be a "tie"—because both sides are unregistered persons who fall within Rule 908(b)—or one side would become the reporting side because only that side includes a person that falls within Rule 908(b).[546] The commenters argued generally that the absence of registered security-based swap dealers at the top of the reporting hierarchy during the Interim Period would create a number of difficulties in negotiating and carrying out reporting duties.[547] Commenters pointed out particular difficulties with ascertaining reporting duties for cross-border transactions under Rule 901(a)(2)(ii) during the Interim Period[548] and emphasized that buy-side U.S. persons that transact with foreign dealing entities during the Interim Period would find it particularly difficult to make assessments of whether their non-U.S. counterparties were engaged in ANE activity. Furthermore, according to the commenters, attempts to address difficulties arising during the Interim Period would be costly, complicated, and inefficient,[549] and such interim solutions would not be useful for the period after the SBS entities registration compliance date.[550]

The Commission acknowledges the commenters' concerns that requiring compliance with Regulation SBSR before the SBS entities registration compliance date would have raised numerous challenges, and that addressing these challenges would have necessitated time and investment to create interim solutions that might not be useful after the SBS entities registration compliance date. Therefore, the Commission has determined that market participants will not be required to comply with Regulation SBSR until after the SBS entities registration compliance date. As noted above, the second prong of Compliance Date 1 is one month after the SBS entities registration compliance date. This one-month period is designed to allow all security-based swap market participants to become familiar with which firms have registered as security-based swap dealers, and for registered security-based swap dealers to ensure that they have the systems, policies, and procedures in place to commence their primary reporting duties under Regulation SBSR. Without providing an additional period between the SBS entities registration compliance date and Compliance Date 1, unnecessary confusion could result if market participants were forced to readjust their reporting hierarchies within a very short period, particularly if several firms were to register only days before or actually on the SBS entities registration compliance date.

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[543] Every security-based swap in that asset class that is executed on or after July 21, 2010, and up and including to the day immediately before Compliance Date 1 is a transitional security-based swap. As discussed in Section X(E), *infra,* the Commission's final compliance schedule establishes a separate Compliance Date 3 for pre-enactment and transitional security-based swaps.

[544] Rule 904(d) addresses how a registered SDR must publicly disseminate information about security-based swap transaction reports that were submitted during its closing hours. As discussed in Section X(D), *infra,* public dissemination will commence on Compliance Date 2.

[545] One commenter submitted several comments regarding this issue. *See* ISDA I at 4, 11–13; ISDA II at 1–14; ISDA III at 1–2, 9–12; ISDA/SIFMA Letter at 6–9. Other commenters raised similar issues. *See* IIB Letter at 17; SIFMA–AMG II at 6–7; SIFMA/FSR Letter at 15.

[546] If one side of a security-based swap includes no person that falls within Rule 908(b), that side does not incur any reporting duties under Regulation SBSR.

[547] *See, e.g.,* ISDA I at 11–13; ISDA II at 1–12; ISDA III at 1–2; ISDA/SIFMA at 6–7.

[548] *See* ISDA II at 1–10; ISDA III at 2–11; SIFMA/FSR Letter at 13–14; SIFMA–AMG II at 6–7. One commenter expressed the general view that costs to buy-side U.S. persons of negotiating with counterparties regarding reporting responsibilities, constructing reporting mechanisms, or engaging third parties to aid in their reporting are substantial and outweigh the benefits of beginning reporting prior to the SBS entities registration compliance date. *See* ISDA II at 4.

[549] One commenter, for example, presented a complex set of possible options for facilitating industry compliance with Regulation SBSR during the Interim Period. *See* ISDA III, *passim.* These suggestions included the Commission adopting an "interim reporting side hierarchy" as well as "a publicly available industry declaration for entities willing to assume the role of a SBS dealing entity in such hierarchy," regardless of whether or not they were engaging in ANE activity in a particular transaction. *See id.* at 9–10. The commenter also provided a detailed discussion of potential costs associated with these suggested interim solutions. *See id.* at 6–9.

[550] *See, e.g.,* ISDA II at 7; UBS Letter at 2; ISDA/SIFMA Letter at 9 (arguing that requiring compliance with the reporting duties before the SBS entities registration compliance date "creates unjustified additional costs to implement interim solutions" and that "[t]he cost and effort of such implementation will be wasted once dealer registration is required"). This commenter presented several potential alternatives for addressing concerns about implementing Regulation SBSR before the SBS entities registration compliance date, while stressing that its first choice was for the Commission to delay Compliance Date 1 until after the SBS entities registration compliance date. *See* ISDA III at 3–5, 9–10.

One commenter who urged that the Commission defer compliance with Regulation SBSR until after security-based swap dealers register also recommended that, "[i]f the Commission decides to require regulatory reporting of ANE transactions despite [comments] to the contrary, reporting should be required only with respect to those ANE transactions that are relevant for SBSD registration (*i.e.*, executed from the later of (a) February 21, 2017 or (ii) two months before the SBS registration compliance date)." [551] In light of the Commission's final Compliance Date 1 schedule, this comment is now moot because dealing entities will not be required to report any security-based swap transactions before the SBS entities registration compliance date.

2. At Least Six Months Between First SDR To Register and Compliance Date 1

Final Compliance Date 1 retains a prong that generally follows the principle in proposed Compliance Date 1 of allowing six months between the registration of the first SDR that can accept transaction reports of security-based swaps in an asset class. The Commission continues to believe that it is appropriate to give market participants at least six months after the registration of the first SDR that can accept transaction reports of security-based swaps in an asset class before they are required to report transactions in that asset class. This period will enable market participants to prepare their systems for reporting to that SDR and to fully familiarize themselves with the SDR's policies and procedures. However, as discussed below, final Compliance Date 1 eliminates the proposed reference to the date on which such SDR "commences operations" as a registered SDR.

One commenter expressed the view that the proposed compliance timeline would give reporting sides and SDRs adequate time to implement Regulation SBSR.[552] A second commenter, however, argued that Compliance Date 1 should be extended to 12 months after the registration of the first SDR in an asset class.[553] A third commenter recommended that Compliance Date 1 be nine months after the later of (1) the date by which security-based swap dealers and major security-based swap participants are required to register with the Commission; and (2) the date on which the Commission announces SDR readiness in an asset class.[554]

The Commission believes that six months is an appropriate minimum period between registration of the first SDR in an asset class and Compliance Date 1 with respect to that asset class, particularly in view of the Commission's decision not to require compliance with Regulation SBSR until after the SBS entities registration compliance date. The Commission further notes that, before the Commission grants registration to any SDR, the application would be published for comment.[555] The minimum six-month period between the Commission's grant of an SDR's registration and Compliance Date 1 should allow prospective participants sufficient time to analyze the final form of the SDR's policies and procedures under Regulation SBSR, make inquiries to the SDR about technological and procedural matters for connecting to the SDR to report the necessary data, build or adapt existing connections as necessary, and conduct systems testing.[556] The Commission staff intends to monitor participant readiness during the period between the granting of the first SDR registration and Compliance Date 1.

Certain commenters suggested establishing dates certain for compliance with Regulation SBSR.[557] While the Commission appreciates commenters' desire to have certainty about when their duties under Regulation SBSR will commence, the Commission notes that there are not yet any registered SDRs and the Commission cannot predict when one or more SDRs will be granted registration. Furthermore, the SBS entities registration compliance date is contingent on the completion of several other rulemakings. The Commission believes, therefore, that the more practical approach is to base Compliance Date 1 on the later of these two events, rather than to establish dates certain.

Finally, two commenters noted that, although proposed Compliance Date 1 would have been tied to the commencement of operations of a registered SDR in an asset class, "commencement of operations" is not defined and it was not clear to the commenters how this date would be determined or how market participants would be made aware of that date.[558] The Commission has determined to eliminate the "commencement of operations" as one of the triggering events in Compliance Date 1. The Commission acknowledges that this change from "commencement of operations" to the date of SDR registration in this prong could reduce the number of days between the issuance of this release and Compliance Date 1, if there is in fact a lag between registration and the "commencement of operations" for that registered SDR. However, the Commission believes that market participants will benefit from eliminating uncertainty about precisely when an SDR "commences operations" and how the fact of such commencement would be conveyed.

Finally, the Commission notes that it is setting Compliance Date 1 as *the first Monday* following the later of the two stipulated events. Beginning mandatory transaction reporting on a Monday will give registered SDRs and their participants at least one final weekend to conduct any final systems changes or testing.

3. There May Be Separate Compliance Dates for Separate Asset Classes

The Commission is adopting the proposed approach that the compliance dates are specific to a security-based swap asset class. One commenter expressed concern that the potential for varying compliance dates for different asset classes "would inject unnecessary complexity into the implementation process and potentially cause confusion among market participants.'' [559] The Commission notes, however, that there is no requirement that a person that seeks registration as an SDR must accept security-based swaps in both the credit and equity asset classes. Thus, a person might submit an application to register as an SDR only with respect to a single asset class.[560] If the Commission were to grant registration of an SDR applicant that could receive transactions in only a single asset class and assuming that the other prong of Compliance Date 1 were met, it would be impossible for market participants to report transactions in other asset classes to that SDR. Delaying Compliance Date 1 until an SDR has been registered in all security-based swap asset classes would prevent reporting from beginning in the asset class or classes that the first registered SDR is ready to accept. Therefore, the Commission believes that it is appropriate to make the compliance dates specific to each asset class.

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[551] UBS Letter at 3.

[552] *See* ICE Letter at 7.

[553] *See* LCH.Clearnet Letter at 4, 12–13. The commenter believed that the proposed timeframe would not provide enough time to connect to all registered SDRs. *See id.* at 4.

[554] *See* ISDA/SIFMA Letter at 17; UBS Letter at 2.

[555] *See* SDR Adopting Release, 80 FR at 14465.

[556] *See* WMBAA Letter at 6 ("Platforms' compliance with the Proposed Rules will depend on the permissibility of functionality of services provided by third-party vendors and SDRs. These vital infrastructure components will determine how quickly platforms and market participants can comply with the Proposed Rules").

[557] *See* DTCC Letter at 3; DTCC/ICE/CME Letter at 4.

[558] *See* DTCC Letter at 12; ISDA/SIFMA Letter at 17.

4. ''First-Mover'' Concerns

Several commenters expressed concerns about triggering compliance based on the first SDR in an asset class to register with the Commission.[561] One commenter recommended that, to minimize these concerns, the Commission should ''coordinate its processing of SDR applications received within a reasonable window and time its announcement of SDR registration and readiness to include all SDRs for an asset class that will be approved ahead of Compliance Date 1.'' [562] Likewise, a second commenter urged the Commission ''to uniformly review and approve SDR applicants that are acting in good faith to complete the application process in order to minimize 'first mover' advantages.'' [563]

With respect to commenters' concerns about multiple SDR applications for registration, the Commission previously stated in the SDR Adopting Release that it ''intends to process such applications . . . within the same period of time so as to address competition concerns that could arise if such SDRs were granted registration at different times.'' [564] However, if an SDR application meets the criteria of Rule 13n–1(c)(3) under the Exchange Act,[565] the Commission does not believe that it should be necessary to delay granting the registration because of the status of other pending applications. As the Commission also noted in the SDR Adopting Release: ''Certain unexpected events that raise compliance concerns with respect to one applicant but not another, such as deficiencies identified in connection with the Commission's consideration of whether an applicant meets the criteria of Rule 13n–1(c), may interfere with the Commission's ability to process initial applications for registration within the same period of time.'' [566]

The Commission acknowledges that, by requiring compliance based on the first SDR in an asset class to register with the Commission, a participant might not be able to report security-based swaps to its preferred SDR. However, this situation implies that the participant's preferred SDR for reporting security-based swap transactions has not yet met the criteria for registration under Rule 13n–1(c)(3). The Commission believes that commencing reporting with only a single registered SDR in an asset class, should this prove necessary, would be preferable to any alternative. When the Commission grants the first SDR registration, delaying compliance with Regulation SBSR until additional registrations are granted would not further the objectives of Title VII.[567] The opposite approach, whereby the Commission would not require compliance with Regulation SBSR until two or more SDRs had registered with the Commission, could have the effect of giving an applicant that has not met the criteria for registration the power to delay the reporting regime contemplated by Title VII. The Commission believes that this outcome would unfairly retard the ability of a successful applicant to begin providing SDR services.

Finally, the Commission notes that, even if there is only one registered SDR for some period of time, other Commission rules are designed to minimize any undue advantage that the first SDR might otherwise enjoy. For example, every SDR, even the first and only registered SDR in a particular asset class, must offer fair, open, and not unreasonably discriminatory access to users of its services.[568] Furthermore, any fees that it charges would have to be fair and reasonable and not unreasonably discriminatory.[569]

5. No Delay for Substituted Compliance Determinations

Three commenters urged the Commission to defer compliance with Regulation SBSR until the Commission has made substituted compliance determinations with respect to regulatory reporting and public dissemination of security-based swap transactions for certain foreign jurisdictions.[570] In the view of one of these commenters, this approach could ''save reporting sides the effort and cost of building to the SBSR requirements if their current builds will suffice.'' [571] Another commenter stated that ''[r]equiring the changes to systems, personnel and trade flows necessary to comply with the Commission's Proposal only to later be granted substituted compliance would impose significant and unnecessary burdens for negligible short-term benefits.'' [572]

The Commission declines to accept this suggestion and does not believe that compliance with Title VII's regulatory reporting and public dissemination requirements, as implemented by Regulation SBSR, should be delayed until the Commission has made any substituted compliance determinations. The Commission has not yet received any substituted compliance applications and, therefore, does not yet have sufficient information regarding any foreign jurisdiction to make the findings necessary to issue a substituted compliance order. In addition, because many other jurisdictions are, like the Commission, still in the process of establishing and implementing their regulatory requirements, the Commission cannot predict when—or even if—any jurisdictions ultimately will have regulatory systems that are comparable to Regulation SBSR. If the Commission were to accept the commenters' suggestion, the Commission might have to defer compliance for a lengthy period, which would unnecessarily delay the implementation of the reporting and public dissemination regime.

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[559] DTCC Letter at 12, n. 25.

[560] *See* Securities Exchange Act Release No. 77699, Notice of Filing of Application for Registration as a Security-Based Swap Data Repository by ICE Trade Vault, LLC (April 22, 2016) (SBSDR–2016–01) (requesting registration with the Commission as an SDR only for the credit asset class).

[561] *See* DTCC Letter at 12 (noting that market participants will likely be compelled to begin the onboarding process with the first registered SDR); DTCC/ICE/CME Letter at 4 (noting that market participants would have no choice but to join the first registered SDR to guarantee that they meet any compliance date tied to the first SDR); ICE Letter at 8; ISDA/SIFMA Letter at 18 (stating that a reporting side may not be able to freely select the SDR of its choice if another SDR is first to register and the desired SDR cannot complete the registration process before participants would be compelled to report to the first SDR).

[562] ISDA/SIFMA Letter at 18.

[563] ICE Letter at 8. This commenter also urged the Commission to ''focus equally on each application,'' ''provide applicants equal opportunities to address the Commission's comments and amend their applications,'' and ''make best efforts to approve SDR applicants at the same time.'' *Id.*

[564] 80 FR at 14467.

[565] 17 CFR 240.13n–1(c)(3) (enumerating the criteria that the Commission must assess in granting the registration of an SDR).

[566] 80 FR at 14467, n. 340.

[567] *See, e.g.,* S. Comm. on Banking, Hous., & Urban Affairs, The Restoring American Financial Stability Act of 2010, S. Rep. No. 111–176, at 32 (''As a key element of reducing systemic risk and protecting taxpayers in the future, protections must include comprehensive regulation and rules for how the OTC derivatives market operates. Increasing the use of central clearinghouses, exchanges, appropriate margining, capital requirements, and reporting will provide safeguards for American taxpayers and the financial system as a whole'').

[568] *See* Rule 13n–4(c)(1)(iii) under the Exchange Act, 17 CFR 240.13n–4(c)(1)(iii).

[569] *See* Rule 13n–4(c)(1)(i) under the Exchange Act, 17 CFR 240.13n–4(c)(1)(i).

[570] *See* ISDA/SIFMA Letter at 19–20; SIFMA/FSR Letter at 12–13, 15 (recommending deferring compliance until the Commission makes comparability determinations for ''key'' foreign jurisdictions including Australia, Canada, the European Union, Japan, and Switzerland); IIB Letter at 19.

[571] ISDA/SIFMA Letter at 20.

[572] SIFMA/FSR Letter at 15.

6. No Delay for Adoption of SB SEF Rules

Two commenters urged the Commission to delay Compliance Date 1 until the Commission adopts final rules relating to SB SEFs and provides sufficient time for entities to register with the Commission as SB SEFs.[573] One of these commenters argued, for example, that "the Commission should prepare alternative compliance regimes in the chance that all of the SB swap trading rules are not in place (and, as a result, market participants cannot meet the reporting obligations of Rule 901) by Compliance Date 1." [574]

The Commission declines to act on the commenters' suggestion. Delaying compliance with Regulation SBSR until final rules relating to SB SEFs are adopted would result in the Commission and other relevant authorities continuing to lack complete records of all security-based swap transactions, which will facilitate market and systemic risk oversight. The Commission believes that Regulation SBSR can be successfully implemented even before the adoption of final SB SEF rules and the registration of SB SEFs with the Commission. The Commission understands that, currently, many security-based swaps trade off-platform and it is likely that a sizeable portion of the security-based swap market will continue to trade off-platform, even after SB SEFs have the opportunity to register with the Commission. The Commission believes that delaying Compliance Date 1 until SB SEFs have registered would unnecessarily delay the reporting of security-based swaps that trade off-platform.

The Commission understands that there are a small number of existing entities that likely meet the definition of "security-based swap execution facility" at present but are not yet registered with the Commission as such. However, Rule 901(a)(1) applies to all platforms, including unregistered SB SEF. Moreover, the Commission does not believe that the finalization of its SB SEF rules would affect their capability to report such transactions to a registered SDR because the Commission understands that such entities are likely to be swap execution facilities that already have incurred swap reporting duties under CFTC rules.[575] Thus, these entities already have substantial reporting infrastructure that can likely be used to support security-based swap reporting duties.[576] For transactions that occur on exempt SB SEFs, the Commission considered an alternative of requiring a side to report each transaction effected on the SB SEF that will be submitted to clearing until SB SEFs have an opportunity to register with the Commission. However, this alternative is unworkable because platform transactions that will be submitted to clearing may be anonymous, and the sides cannot be expected to ascertain the reporting side or report the necessary counterparty information if they are anonymous to each other.[577]

7. Compliance With UIC Requirements

Several commenters urged the Commission to defer compliance with Regulation SBSR's UIC requirements until international standards for these UICs are developed and can be used across multiple SDRs and multiple jurisdictions.[578] Two of these commenters expressed concern that requiring each registered SDR to establish its own UIC system ahead of an internationally recognized standard would generate significant complexities and costs and would frustrate data aggregation efforts.[579] One commenter argued that the Commission generally should "consider a separate compliance schedule for UIC fields to allow sufficient time for SB SDRs to work collaboratively with market participants, including prospective UIC issuers, to develop an industry standard or, at minimum, an SB SDR-specific methodology." [580]

After carefully considering the issues raised by commenters, the Commission believes, for the reasons described below, that use of the various UICs must commence on Compliance Date 1:

a. UICs for Legal Entities

For any UIC that can be represented with a Legal Entity Identifier ("LEI"), compliance is required on Compliance Date 1. In the Regulation SBSR Adopting Release, the Commission recognized the Global Legal Entity Identifier System ("GLEIS") as an internationally recognized standards-setting system ("IRSS") that satisfies the requirements of Rule 903.[581] Under Rule 903(a), if an IRSS recognized by the Commission has assigned a UIC to a person, unit of a person, or product, each registered SDR must employ that UIC for reporting purposes under Regulation SBSR, and SDR participants must obtain such UICs for use under Regulation SBSR. Counterparties, ultimate parents, brokers, execution agents, platforms, registered clearing agencies, and registered broker-dealers typically are legal entities and typically already have or will be able to obtain an LEI. Accordingly, compliance with the LEI requirements under Regulation SBSR is required on Compliance Date 1.

b. Branch ID, Trading Desk ID, and Trader ID

Regulation SBSR also requires UICs for three types of "sub-legal entities": Branches, trading desks, and individual traders. As commenters note, neither the GLEIS nor any other potential IRSS assigns identifiers to any sub-legal entities at this time.[582] Although the GLEIS has begun exploring the possibility of assigning identifiers to branches and certain natural persons,[583] it is unclear when any final decision to do so might be taken. Given the uncertainty about when or even if an IRSS will eventually be able to issue identifiers for all branches, trading desks, and traders, the Commission does not believe that it would be appropriate to delay compliance with these UIC requirements until an IRSS can provide them.

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[573] *See* WMBAA Letter at 5–6; ISDA/SIFMA Letter at 3.

[574] WMBAA Letter at 6.

[575] *See* Swap Data Recordkeeping and Reporting Requirements, 77 FR 2136 (January 13, 2012) (discussing reporting under the CFTC rules and swap execution facilities roles in that reporting); *see also* "The Role of Swap Execution Facilities (SEFs) in Derivatives Trade Execution, Clearing and Reporting: Part 2" at *https://riskfocus.com/the-role-of-swap-execution-facilities-sefs-in-derivatives-trade-execution-clearing-and-reporting-part-2/* (last visited on May 25, 2016) for a summary of such reporting.

[576] *See supra* Section IV(H).

[577] *See supra* Section IV(B).

[578] *See* DTCC Letter at 2–3; ISDA/SIFMA Letter at 3, 12; DTCC/ICE/CME Letter at 3–4; Financial InterGroup Letter at 4.

[579] DTCC Letter at 10; DTCC/ICE/CME Letter at 3.

[580] DTCC Letter at 11. *See also* DTCC/ICE/CME Letter at 3 (stating that the Commission should allow "sufficient time for the IDs to be developed in collaboration with the industry").

[581] *See* 80 FR at 14631–32.

[582] *See* DTCC Letter at 9–10; Financial InterGroup Letter at 3–4.

[583] *See, e.g.,* LEI Regulatory Oversight Committee, "Consultation document on including data on branches in the Global LEI System," available at *http://www.leiroc.org/publications/gls/lou_20151019-1.pdf* (last visited on May 25, 2016); and "Statement on Individuals Acting in a Business Capacity," available at *http://www.leiroc.org/publications/gls/lou_20150930-1.pdf* (last visited on May 25, 2016).

The Commission recognizes that this approach raises the possibility that different SDRs could, in theory, assign different UICs to the same person, unit of a person, or product. If this were to occur, the Commission could have to map the UICs assigned by one registered SDR to the corresponding UICs assigned by one or more other SDRs to maintain a complete picture of the market activity pertaining to a particular person or sub-legal entity. The Commission specifically addressed this issue in the Regulation SBSR Adopting Release.[584] However, the Commission previously noted a mechanism whereby a participant could use the same UICs at multiple SDRs.[585] Regulation SBSR does not prohibit a participant from making suggestions to a registered SDR regarding the UICs that the SDR is required to assign, particularly for sub-legal entities.[586] Through this mechanism for assignment, a person who is a participant of two or more registered SDRs could—with the concurrence of these SDRs—utilize the same UICs across multiple SDRs.[587]

c. Transaction ID

Also beginning on Compliance Date 1, each registered SDR must comply with Rule 901(g), which requires the SDR to assign a transaction ID to each security-based swap, or establish or endorse a methodology for transaction IDs to be assigned by third parties. Because of the potential importance of identifying individual transactions for systemic risk and market oversight purposes, the Commission believes that it is essential for registered SDRs to comply with Rule 901(g) from the moment that they begin receiving mandatory transaction reports.[588]

One commenter expressed the belief that SDRs will be able to assign transaction IDs to pre-enactment and transitional security-based swaps by the date that the Commission had proposed in the Regulation SBSR Proposed Amendments Release.[589] Since the proposed compliance schedule would have required historical security-based swaps to be reported by or before proposed Compliance Date 1, the comment implies that registered SDRs also should be able to assign transaction IDs to newly executed transactions beginning on Compliance Date 1.

A second commenter urged the Commission to "recognize the 'first touch principle' as an acceptable standard for SB SDRs to meet their 901(g) obligations." [590] The commenter explained that, under the existing CFTC swap data reporting rules, an SDR is not required to issue a transaction ID and can rely on the reporting side to submit its internal transaction ID.[591] As provided in existing Rule 901(g), a registered SDR may endorse a methodology for third parties to assign a transaction ID to an individual security-based swap. If an SDR wishes to allow third parties (such as platforms or counterparties) to assign transaction IDs, the SDR must explain in its policies and procedures under Rule 907(a)(5)[592] any form or content requirements imposed by the SDR that the third party would be required to follow.

d. Product ID

One commenter argued that, before requiring compliance with the product ID requirement, the Commission should "consult and agree with market participants on a standard to be applied. An agreed upon public standard would provide greater certainty to reporting sides and SB SDRs to build to one uniform standard as opposed to bespoke models for each SDR." [593] After careful consideration of this comment, the Commission has determined not to delay compliance with the product ID requirement. At the present time, it is unclear if or when market participants could agree upon and implement standards for a product ID. Therefore, in the absence of an IRSS that can assign product IDs, registered SDRs must by Compliance Date 1 begin assigning product IDs, and persons with a duty to report transactions must use these SDR-assigned product IDs in their mandatory reports. To enable their participants to report transactions using the appropriate product IDs on Compliance Date 1, registered SDRs must set out in their written policies and procedures how they will assign product IDs (and all other UICs other than those available through an IRSS recognized by the Commission) in a manner consistent with Rule 903. A registered SDR should consider publishing as far in advance of Compliance Date 1 as possible the product IDs of the products most likely to be traded on or shortly after Compliance Date 1. The Commission recognizes, however, that it is not practical for a registered SDR to publish a list of all possible products with their product IDs, as many products have not yet been created (or certain types of contracts have not yet become sufficiently standardized as to become products, as that term is defined in Rule 900(aa), and thus require a product ID). Therefore, as a practical matter, the Commission does not believe that a registered SDR could comply with Rule 907(a) unless its policies and procedures include a mechanism or process for the registered SDR to assign a product ID to a new product before or simultaneously with the initial transaction in that product, and to make available the product ID so that reports of transactions in that new product can include the correct product ID.

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[584] *See* 80 FR at 14632 ("UICs, even if SDR-specific, will provide a streamlined way of reporting, disseminating, and interpreting security-based swap information. The Commission believes that requiring registered SDRs to develop their own UICs—but only for UICs that are not assigned by or through an IRSS that has been recognized by the Commission—will result in less confusion than the currently available alternatives, such as allowing each reporting side to utilize its own nomenclature conventions, which would subsequently have to be normalized by registered SDRs or by the Commission").

[585] *See* Regulation SBSR Adopting Release, 80 FR at 14723, n. 1371 ("assume that a person becomes a participant of a registered SDR and obtains UICs for its trading desks and individual traders from that SDR. Later, that person becomes a participant at a second registered SDR. The second SDR could issue its own set of UICs for this person's trading desks and individual traders, or it could recognize and permit use of the same UICs that had been assigned by the first registered SDR").

[586] This could also be true for identifying counterparties that do not fall within Rule 908(b) and do not otherwise have an LEI that could be used for the counterparty ID.

[587] In connection with its comments regarding how Regulation SBSR's compliance dates should address UIC issues, one commenter recommended that the Commission "consult and agree with market participants" on how to assign various UICs, including branch ID, trading desk ID, trader ID, and product IDs. *See* DTCC Letter at 10–11. The commenter then recommended compliance dates of different lengths after a standard for each type of UIC had been agreed upon. *See id.* The Commission already has established a mechanism for how these UICs must be assigned: Rule 903(a), as adopted in the Regulation SBSR Adopting Release, provides that, in the absence of a Commission-recognized IRSS that can supply the UIC, a registered SDR must assign the UIC using its own methodology. Furthermore, in light of the guidance above regarding how a registered SDR may confer with a participant to assign a mutually agreeable set of UICs—and how, through this process, the same UICs could be used for a particular participant across multiple SDRs—the Commission does not believe that it is necessary or appropriate to establish different compliance dates for each type of UIC in the manner recommended by the commenter.

[588] Also beginning on Compliance Date 1, each registered SDR must comply with the companion requirement in Rule 901(f) that a registered SDR time-stamp all incoming transaction reports.

[589] *See* ICE Letter at 8.

[590] DTCC Letter at 20.

[591] *See id.* The Commission notes, however, that, under CFTC Rule § 45.5(c), 17 CFR 45.5(c), a swap data repository must create and transmit a unique swap identifier for an off-facility swap if the reporting counterparty for that swap is a non-swap dealer/major swap participant.

[592] Rule 907(a)(5) requires a registered SDR to establish and maintain written policies and procedures for assigning UICs, including but not limited to transaction IDs, in a manner consistent with Rule 903.

[593] DTCC Letter at 10.

8. Switching of Reporting Side Designation

One commenter's analysis of the problems that could result from a Commission determination to require reporting compliance ahead of the SBS entities registration compliance date was premised on the assumption that a U.S. non-dealing entity that was the reporting side for a security-based swap executed during the Interim Period would remain the reporting side for the life of the security-based swap.[594] The commenter argued that Regulation SBSR should not permit the reporting side designation to "switch" from one side to the other over life of a security-based swap contract.[595] The Commission disagrees with this comment.

Rule 901(a)(2)(ii) sets forth a reporting hierarchy that has two possible outcomes for any transaction pair: (1) One side occupies a higher rung in the hierarchy than the other side, in which case the side that occupies the higher rung "shall be the reporting side"; or (2) the outcome is a tie, and "the sides shall select the reporting side." Sides in a tie situation, after having made an initial selection of the reporting side, can select a new reporting side later in the life of the contract.[596]

Over the life of a security-based swap, a registered SDR needs to know the reporting side of a security-based swap so that it knows whether it is receiving a report of a life cycle event or an error report from the entity that is obligated to report that information. A registered SDR should consider incorporating into its policies and procedures how it would accommodate any change to the reporting side designation. A registered SDR may, for example, seek to obtain, in the case of an elective switch, information from one or both sides that confirms the switch.

D. Compliance Date 2

Compliance Date 2 is the date on which all registered SDRs that can accept security-based swaps in a particular asset class must begin public dissemination, pursuant to Rule 902, of transactions in that asset class. On Compliance Date 2, each such SDR will be required to comply with Rules 902 (regarding public dissemination generally), 904(d) (requiring dissemination of transaction reports held in queue during normal or special closing hours), and 905(b)(2) (with respect to public dissemination of corrected transaction reports) for all security-based swaps in that asset class, except as provided by Rule 902(c). As discussed further below, Compliance Date 2 is the first Monday that is three months after Compliance Date 1.

One commenter expressed the view that commencing the requirement for public dissemination nine months after SDR registration would be sufficient, provided that other compliance issues arising earlier in the compliance schedule are resolved.[597] Likewise, a second commenter believed that Compliance Date 2 should be three months after Compliance Date 1, but only after stating its belief that Compliance Date 1 should be 12 months rather than six months after the first registered SDR commences operations.[598] A third commenter believed that three months after Compliance Date 1 was not sufficient time for SDRs to comply with the data dissemination requirements in Regulation SBSR and recommended six months instead.[599] A fourth commenter recommended that Compliance Date 2 be three months after the later of Compliance Date 1 and the date on which the Commission has determined appropriate exceptions, delays, and/or notional caps to preserve the identity, business transactions, and market positions of any person.[600] The fourth commenter asserted that the longer time was necessary for Compliance Date 2 because "concerns regarding the compromise of market anonymity for illiquid and large notional trades have not adequately been addressed during the interim period." [601]

The Commission has revised its proposed approach to Compliance Date 2 as it relates to the handling of covered cross-border transactions. In the Regulation SBSR Proposed Amendments Release, the Commission proposed that the public dissemination requirements associated with Compliance Date 2 would not have applied to covered cross-border transactions.[602] However, as discussed in Section IX(E), *supra,* the Commission in the U.S. Activity Proposal sought additional comment on whether public dissemination of covered cross-border transactions should be made effective [603] and, in this release, the Commission has determined that all transactions described in Rule 908(a)(1), including covered cross-border transactions, shall be subject to public dissemination, except as otherwise provided by Rule 902(c). Therefore, compliance with the public dissemination requirements shall commence on Compliance Date 2 for covered cross-border transactions along with other security-based swaps, and there is no longer any reason to consider an effective or compliance date for covered cross-border transactions separate from all other transactions that are subject to public dissemination.

The Commission proposed and is now adopting a three-month period between Compliance Date 1 and Compliance Date 2. This three-month period is designed to give registered SDRs and persons having a duty to report an opportunity to identify and resolve any issues related to trade-by-trade reporting by participants and further test their data dissemination systems. The Commission staff intends to monitor the implementation of Regulation SBSR between Compliance Dates 1 and 2.

Also, similar to the approach taken for Compliance Date 1, the Commission believes that it will be helpful to the industry to begin public dissemination on a Monday, which ensures that registered SDRs have at least the immediately preceding weekend to conduct any final systems changes or testing before public dissemination begins. Therefore, Compliance Date 2 is the first Monday that is three months after Compliance Date 1.

Finally, Compliance Date 2 is the date by which participants of registered SDRs that are subject to Rule 906(b) must comply with that rule.[604] This represents a change from the proposed compliance schedule, under which covered participants would have been required to comply with Rule 906(b) on Compliance Date 1.[605] A person does not become subject to Rule 906(b) until it becomes a participant of a registered SDR. A counterparty to a security-based swap becomes a participant of a registered SDR only when a security-based swap to which it is a counterparty is reported to that SDR on a mandatory basis.[606] Thus, a security-based swap counterparty cannot become a participant until Compliance Date 1 at the earliest, because transactions will not be reported to a registered SDR on a mandatory basis until Compliance Date 1. A large number of security-based swap counterparties will become participants on Compliance Date 1 or the first days and weeks following Compliance Date 1. This could, in the Commission's view, cause unnecessary difficulties for registered SDRs and their new participants if participants were required to comply with Rule 906(b) on Compliance Date 1.[607]

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[594] *See* ISDA I at 13; ISDA II at 7.

[595] *See* ISDA I at 8 ("Switching the reporting side during the term of a trade is in every respect an enormous challenge . . . [and] will likely have a significant impact on the completeness, integrity and correctness of reported SBS data").

[596] If the sides insisted on selecting a new reporting side but Rule 901(a)(2)(ii) did not permit them to do so, they could accomplish the new selection by tearing up the existing security-based swap and immediately replacing it with a new security-based swap having exactly the same terms, except that they select a different reporting side for the new transaction.

[597] *See* DTCC Letter at 21.

[598] *See* LCH.Clearnet Letter at 12.

[599] *See* ICE Letter at 8.

[600] *See* ISDA/SIFMA Letter at 17.

[601] ISDA/SIFMA Letter at 3.

[602] *See supra* note 460 (explaining that term). One commenter supported excluding covered cross-border transactions from public dissemination on Compliance Date 2, as well as the Commission's decision to seek public comment before determining if and when to include them in the scope of transactions subject to public dissemination. *See* ISDA/SIFMA Letter at 18. The Commission addressed this comment in Section IX(E), *supra.*

[603] *See* 80 FR at 27485.

[604] Rule 906(b) requires each participant of a registered SDR to provide to the SDR information sufficient to identify the participant's ultimate parent(s) and any affiliate(s) of the participant that also are participants of that registered SDR. Rule 906(b) further provides that a participant must "promptly" notify the registered SDR of any

In light of this concern, the Commission now believes that it is appropriate to delay compliance with Rule 906(b) for an additional three months to avoid triggering a large number of new filings and amendments that likely would have been required if the Commission had required compliance with Rule 906(b) on Compliance Date 1. Accordingly, the Commission is not requiring compliance with Rule 906(b) until Compliance Date 2. This will allow for a number of security-based swaps to be reported over the three-month period between Compliance Dates 1 and 2 that will create a critical mass of participants, thereby permitting the filing of initial reports under Rule 906(b) that are less likely to require repeated updating because of the addition of new participants that are affiliated with existing participants.[608]

E. New Compliance Date 3 for Historical Security-Based Swaps

In the Regulation SBSR Proposed Amendments Release, the Commission proposed that persons with a duty to report historical security-based swaps in the relevant asset class would have been required to report these transactions to a registered SDR that accepts transactions in that asset class, in accordance with Rule 901(i), by Compliance Date 1. As discussed further below, the Commission is adopting a new Compliance Date 3 for the reporting of historical security-based swaps. Compliance Date 3 is two months after Compliance Date 2.

One commenter expressed the view that requiring reporting of historical security-based swaps in advance of the SBS entities registration compliance date would place the bulk of the reporting burden on U.S. persons, including buy-side U.S. persons, because U.S. persons would be the reporting side for all historical security-based swaps entered into with a foreign dealing entity that did not involve ANE activity.[609] Furthermore, this commenter expressed concern that it could not be reliably determined whether U.S. personnel were used to engage in ANE activity for historical security-based swaps because parties were not required to capture or exchange such information at the time the transactions were executed.[610] The commenter concluded that it would be significantly easier to ascertain the reporting side for historical transactions after the SBS entities registration compliance date, because most would involve a counterparty that will register as a security-based swap dealer.[611] This commenter, in a joint letter with another association, also expressed the view that the volume of non-live historic security-based swaps "will be enormous" and that "reporting over five years of security-based swap transaction data will require tremendous effort and coordination between reporting sides and their SDR."[612] These comments recommended an extended period for reporting non-live historical security-based swaps after the SBS entities registration compliance date, and argued that the commencement of reporting under Regulation SBSR would be more effective if the reporting of non-live historic security-based swaps were done separately and after security-based swap dealer registration.[613]

These commenters also argued that "[d]ealer registration will greatly expand the scope of SBS subject to reporting at a later date, essentially creating additional individual compliance dates for registrants and their counterparties to report additional SBS activity and historic SBS," which "will also trigger the question as to who has the reporting obligation for

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changes to that information. Rule 907(a)(6) requires each registered SDR to establish and maintain written policies and procedures for periodically obtaining from each participant information that identifies the participant's ultimate parent(s) and any participant(s) with which the participant is affiliated.

[605] *See* Regulation SBSR Proposed Amendments Release, 80 FR at 14765.

[606] *See* Rule 900(u).

[607] For example, assume that S, T, and U are affiliated and all have a single ultimate parent (P) and the Commission had required compliance with Rule 906(b) on Compliance Date 1. At 09:30:02 UTC on Compliance Date 1, a security-based swap involving S as a counterparty is reported to SDR A on a mandatory basis. This is the first time that S is a counterparty to a transaction reported to SDR A on a mandatory basis, and no affiliates of S are counterparties to security-based swaps that have been reported to SDR A. Upon becoming a participant of SDR A, S must report to SDR A that it has an ultimate parent (P) and no affiliates that are also participants. At 10:30:57 UTC, a security-based swap involving T as a counterparty is reported to SDR A on a mandatory basis. T also becomes a participant of SDR A and must report to SDR A that it has an ultimate parent (P) and one affiliate (S) that also is a participant of SDR A. Because Rule 906(b) also requires S to promptly notify SDR A of any changes to its ultimate parent and affiliate information, S must amend its submission to SDR A to reflect that its affiliate T has just become a participant. At 11:30:33 UTC, a security-based swap involving U as a counterparty is reported to SDR A on a mandatory basis. U must report to SDR A that it has an ultimate parent (P) and two affiliates that are participants (S and T). U's becoming a participant also triggers revisions to S and T's reports to reflect that their affiliate U has just become a participant. Thus, the creation of new participants in the first hours and days after Compliance Date 1 could trigger the requirement to file a large number of amended reports under Rule 906(b).

[608] The Commission recognizes, however, that several Rule 906(b) reports could have to be amended to reflect the addition of a new participant, even after Compliance Date 2. For example, assume that ultimate parent P has 20 subsidiaries, each of which is a participant of SDR A. Rule 906(b) requires a report from each subsidiary showing P as the ultimate parent and each of the other 19 subsidiaries as affiliates. Now assume that a new 21st subsidiary of P is a counterparty to a transaction reported to SDR A on a mandatory basis. This would trigger amendments to the existing 20 reports to reflect the addition of a new affiliate participant. Because these reports would be unnecessarily duplicative, the Commission interprets Rule 906(b) as being satisfied if one member of a financial group provides all of the required ultimate parent and affiliate information on behalf of each group member that is a participant of that registered SDR. While the registered SDR could seek to obtain a separate report from each group member that is a participant, the Commission encourages registered SDRs to consider establishing policies and procedures under Rule 907(a)(6) that would allow for abbreviated reporting for the entire group. Such abbreviated group reporting would still be subject to the requirement that any changes be reported to the registered SDR "promptly." Furthermore, a participant in the group would still be subject to a requirement to separately disclose any ultimate parent or affiliate information that differs from that of other members of the group. In the example above, assume that the 17th subsidiary of P is a 50–50 joint venture with Q. Under the approach suggested here, one member of the P group could file an abbreviated Rule 906(b) report on behalf of all members of the P group (that would identify all 20 subsidiaries, including the 17th). However, the 17th subsidiary would be subject to a separate requirement to notify the registered SDR that, unlike all of the other P group affiliates, it has two ultimate parents (P and Q) and would have to identify any additional participant affiliates that it might have through its Q parent.

[609] *See* ISDA II at 10; ISDA III at 2, 4.

[610] *See* ISDA II at 10.

[611] *See id.*

[612] ISDA/SIFMA Letter at 16.

[613] *See id.* at 16–17.

historical SBS."[614] This comment is premised on the correct observation that a historical security-based swap between two unregistered non-U.S. persons, neither of whom engaged in ANE activity, would fall within Rule 908(a) only after one side or the other registers with the Commission as a security-based swap dealer. One of these commenters also expressed the view that "existing TIW functionality cannot be leveraged to accomplish reporting [of historical security-based swaps] in advance of registration."[615] Therefore, in the commenter's view, to satisfy obligations to report historical transactions before the SBS entities registration compliance date, market participants would need to expend "significant effort and cost to develop appropriate new industry agreements, conduct significant outreach to U.S. Persons and build interim reporting logic."[616]

In light of these considerations, the Commission is adopting a new Compliance Date 3, which is designed to minimize the concerns raised by the commenters. Persons with a duty to report historical security-based swaps in an asset class must do so by the date that is two months after Compliance Date 2. To the extent that historical transactions involve a non-U.S. counterparty that is likely to register as a security-based swap dealer, deferring compliance with the requirement to report historical transactions until security-based swap dealers are registered will significantly reduce undue burdens on non-dealing persons who are their counterparties. After the SBS entities registration compliance date, registered security-based swap dealers will be clearly identifiable as such and will bear the responsibility for reporting any historical transactions with unregistered persons to the extent that information about such transactions is available. The two-month gap between Compliance Date 2 and Compliance Date 3 is designed to avoid problems that could arise if registered SDRs and their participants had been required to achieve major compliance milestones on the same day or in close proximity.

The Commission notes that the relevant transactions need not be reported *on* Compliance Date 3, but rather *by* Compliance Date 3. The Commission encourages reporting sides to report historical security-based swaps as far in advance of Compliance Date 3 as possible, to avoid difficulties that might arise if reporting sides attempt to report a large number of historical transactions in the last few days or hours before Compliance Date 3.

The Commission believes that a new Compliance Date 3, occurring after the SBS entities registration compliance date, for reporting of historical transactions represents an appropriate consideration of the benefits of mandatory reporting in light of the likely costs. Before security-based swap dealers register as such with the Commission, the only way a foreign dealing entity could incur any duty under Regulation SBSR is if it were engaging in ANE activity with respect to a particular transaction. The Commission is persuaded by commenters who argued that it could be difficult or impossible to ascertain whether historical transactions of foreign dealing entities involved ANE activity, as information about the involvement of U.S. personnel in particular transactions might not exist or might be difficult to reconstruct for transactions that were executed, in some cases, many years ago.[617] Because the Commission anticipates that foreign dealing entities that account for the vast majority of cross-border transactions will register as security-based swap dealers, the issues associated with identifying whether a foreign dealing entity has engaged in ANE activity will not arise for the vast majority of historical cross-border transactions. After the SBS entities registration compliance date, the reporting hierarchy can easily be applied because at least one side will likely include a registered security-based swap dealer. This approach will minimize instances where unregistered U.S. persons could become the reporting side when they are counterparties with foreign dealing entities.

A registered SDR that accepts reports of transactions in the relevant asset class may allow persons with a duty to report historical transactions in that asset class on a rolling basis at any time after Compliance Date 1. When it begins accepting reports of historical security-based swaps submitted on a mandatory basis, a registered SDR must comply with Rule 901(f) and time-stamp, to the second, any security-based swap data that it receives pursuant to Rule 901(i). The registered SDR also must comply with Rule 901(g) with respect to transaction IDs for each historical security-based swap that it receives.

As participants begin reporting historical security-based swaps to a registered SDR, participants and registered SDRs also must comply with Rules 901(e) and 905 regarding any historical security-based swaps that are so reported. A report of a life cycle event of a historical transaction that relates to information required by Rule 901(c) would trigger public dissemination of the life cycle event if the report is submitted on or after Compliance Date 2.[618]

The Commission notes that registered SDRs and their participants need not comply with Rule 906(a) with respect to historical security-based swaps. Rule 906(a) requires a registered SDR to identify security-based swaps for which the SDR lacks counterparty ID and (if applicable) broker ID, branch ID, execution agent ID, trading desk ID, and trader ID. Regulation SBSR requires reporting of historical security-based swaps only "to the extent that information about such transactions is available"—including information pertaining to the remaining UICs. Because broker IDs, branch IDs, execution agent IDs, trading desk IDs, and trader IDs will not be assigned by registered SDRs until they become operational, these UICs likely will not have existed or been recorded in connection with any historical security-based swaps. Therefore, because these UICs are not applicable to historical security-based swaps, a registered SDR is not required by Rule 906(a) to query non-reporting sides for those UICs with respect to any historical transactions, and non-reporting sides are not required by Rule 906(a) to provide any UICs with respect to historical transactions.

F. No Separate Compliance Dates for Cross-Border Transactions

Compliance Dates 1, 2, and 3 apply equally to all security-based swaps that fall within Rule 908(a), as amended herein, and all security-based swap counterparties that fall within Rule 908(b), as amended herein. Compliance Dates 1, 2, and 3 apply to all transactions contemplated by the reporting hierarchy in Rule 901(a)(2), as amended herein, including the cross-border provisions of new Rule 901(a)(2)(ii)(E). Thus, U.S.-to-U.S. transactions do not have different compliance dates than the cross-border transactions that fall within Rule 908(a).

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[614] *Id.* at 7.

[615] ISDA II at 11.

[616] *Id.*

[617] *See* ISDA II at 10; ISDA/SIFMA Letter at 16–17.

[618] *See* Regulation SBSR Adopting Release, 80 FR at 14609 ("life cycle events relating to the primary trade information of historical security-based swaps must, after the public dissemination requirement goes into effect, be publicly disseminated"). However, an error correction of a historical security-based swap involving Rule 901(c) information would not trigger public dissemination, even after Compliance Date 2. *See id.*

One commenter, responding to the proposed compliance schedule in the Regulation SBSR Proposed Amendments Release, warned that, if the Commission required regulatory reporting before security-based swap dealer registration, U.S. non-dealing entities would incur the reporting duty when they traded against large foreign dealing entities[619] and that U.S.-to-U.S. transactions would be subject to public dissemination before U.S.-to-non-U.S. transactions.[620] As a result, the commenter argued, "U.S. person end-users may avoid trading with other U.S. persons until after dealer registration to avoid their data being publicly disseminated."[621] The commenter concluded that U.S. non-dealing entities' avoidance of other U.S. counterparties would disadvantage U.S. dealing entities and result in less liquidity for U.S. non-dealing entities.[622] The commenter also cautioned that "[w]ith a limited list of counterparties and an even narrower list of dealers to such transactions, public dissemination of this smaller segment of SBS data bears the risk that counterparty identity could be disclosed to the public."[623]

As noted in Section IX, *supra,* the Commission is adopting amendments to Rules 901(a) and 908 substantially as proposed to cover additional types of cross-border transactions, and Compliance Dates 1, 2, and 3 will apply equally to all counterparties that fall within Rule 908(b) and all security-based swaps that fall within Rule 908(a). Thus, because Regulation SBSR's compliance dates for U.S.-to-U.S. transactions are the same as for U.S.-to-non-U.S. transactions, there is no incentive for U.S. counterparties to trade only with non-U.S. persons to avoid any Regulation SBSR requirements.[624]

G. Exemptions Related to the Compliance Schedule

In June 2011, the Commission exercised its authority under Section 36 of the Exchange Act[625] to exempt any person from having to report any pre-enactment security-based swaps, as required by Section 3C(e)(1) of the Exchange Act,[626] until six months after an SDR that is capable of receiving security-based swaps in that asset class is registered by the Commission.[627] In the Regulation SBSR Proposed Amendments Release, the Commission proposed to extend the exemption from the requirement to report pre-enactment security-based swaps to ensure consistency between the proposed compliance schedule and the exemption.[628] Because Compliance Date 1, as proposed in the Regulation SBSR Proposed Amendments Release, would have required the reporting of pre-enactment security-based swaps within six months after the commencement of operations of the first registered SDR in that asset class rather than six months after the date of the registration of the first SDR, the Commission also proposed to extend the exemption from Section 3C(e)(1) exemption to synchronize it with proposed Compliance Date 1.

The Commission received one comment on this aspect of its proposed exemption. The commenter agreed that the exemption for the reporting of pre-enactment security-based swaps should be extended to and terminate on Compliance Date 1.[629]

As discussed above, the Commission is adopting new Compliance Date 3 relating to the reporting of historical security-based swaps, which includes pre-enactment security-based swaps. To harmonize the existing exemption with the compliance date for reporting of pre-enactment security-based swaps, the Commission is exercising its authority under Section 36 of the Exchange Act to exempt any person from having to report any pre-enactment security-based swaps, as required by Section 3C(e)(1) of the Exchange Act, in a particular asset class until Compliance Date 3. The Commission finds that such exemption is necessary or appropriate in the public interest, and is consistent with the protection of investors, because such action prevents the existing exemption from expiring before persons with a duty to report pre-enactment security-based swaps are able and are required to report them to a registered SDR.

In conjunction with the proposed extension of the Section 3C(e)(1) exemption included in the Regulation SBSR Proposed Amendments Release, the Commission also proposed that, with respect to security-based swaps in a particular asset class, the exemption from Section 29(b) of the Exchange Act,[630] in connection with Section 3C(e)(1), would terminate on proposed Compliance Date 1. One commenter agreed with this proposed extension of the Section 29(b) exemption in connection with Section 3C(e)(1).[631] In addition, one commenter asked that the Commission clarify how Section 3C(e)(1) of the Exchange Act relates to the Section 29(b) exemption.[632] The commenter noted that the Commission's Section 29(b) exemption applies to security-based swap entered into on or after July 16, 2011, and that Section 3C(e)(1) applies only to pre-enactment security-based swaps, *i.e.,* those entered into before July 21, 2010.[633]

The Commission confirms that the existing exemption from Section 29(b) set forth in the Effective Date Release applies only to security-based swaps entered into on or after July 16, 2011.[634] Section 3C(e)(1) applies only to pre-enactment security-based swaps.[635] As a result, an extension of the Section 29(b) exemption in connection with Section 3C(e)(1) would have had no effect. Therefore, there is no need for the Commission to revise or extend the exemption from Section 29(b) in connection with Section 3C(e)(1).[636]

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[619] *See* ISDA/SIFMA at 7.

[620] *See id.* at 7–8.

[621] *Id.* at 7.

[622] *See id.* at 7.

[623] *Id.* at 7–8.

[624] The Commission believes that this result is generally consistent with the commenter's statement that "SBS data will be more comprehensive and useful if upon the first day that reporting is required under SBSR, broadly all participants that will be a reporting side will have those obligations and such obligation is evident to all other participants in covered SBS." *Id.* at 6.

[625] 15 U.S.C. 78mm.

[626] 15 U.S.C. 78c–3(e)(1).

[627] *See* Effective Date Release, 76 FR at 36291.

[628] *See* 80 FR at 14765–66.

[629] *See* LCH.Clearnet Letter at 13.

[630] 15 U.S.C. 78cc(b). In the Effective Date Release, the Commission exercised its authority under Section 36 of the Exchange Act to temporarily exempt any security-based swap contract entered into on or after July 16, 2011, from being void or considered voidable by reason of Section 29(b) of the Exchange Act, because any person that is a party to the security-based swap contract violated a provision of the Exchange Act that was amended or added by Subtitle B of Title VII of the Dodd Frank Act and for which the Commission has taken the view that compliance will be triggered by registration of a person or by adoption of final rules by the Commission, or for which the Commission has provided an exception or exemptive relief, until such date as the Commission specifies. *See* Effective Date Release, 76 FR at 36305. Section 29(b) of the Exchange Act provides, in relevant part: "Every contract made in violation of any provision of this title or of any rule or regulation thereunder, and every contract . . . heretofore or hereafter made, the performance of which involves the violation of, or the continuance of any relationship or practice in violation of, any provision of this title or any rule or regulation thereunder, shall be void (1) as regards the rights of any person who, in violation of any such provision, rule, or regulation, shall have made or engaged in the performance of any such contract, and (2) as regards the rights of any person who, not being a party to such contract, shall have acquired any right thereunder with actual knowledge of the facts by reason of much the making or performance of such contract was in violation of any such provision rule or regulation . . ."

[631] *See* LCH.Clearnet Letter at 13.

[632] *See* ISDA/SIFMA Letter at 18.

[633] *See id.*

[634] *See* Effective Date Release, 76 FR at 36305–306.

[635] *See* 15 U.S.C. 78c–3(e)(1).

[636] The same commenter also asked for confirmation that the Commission provided the

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H. Substituted Compliance Requests

Rule 908(c) permits a person that potentially would become subject to Regulation SBSR or a foreign financial regulatory authority to submit a substituted compliance request with respect to the rules of a foreign jurisdiction pertaining to regulatory reporting and public dissemination of security-based swap transactions. The submission of a substituted compliance request is elective; therefore, the Commission is not establishing a "compliance date" for Rule 908(c). Nevertheless, such persons may begin submitting substituted compliance requests pursuant to the requirements of Rule 908(c) upon the effective date of this release.

XI. Paperwork Reduction Act

Certain amendments to Regulation SBSR that the Commission is adopting today contain "collection of information requirements" within the meaning of the Paperwork Reduction Act of 1995 ("PRA").[637] The Commission published notices requesting comment on the collection of information requirements relating to Regulation SBSR in the Regulation SBSR Proposed Amendments Release[638] and the U.S. Activity Proposal[639] and submitted relevant information to the Office of Management and Budget ("OMB") for review in accordance with the PRA.[640] In addition, the Commission adopted portions of Regulation SBSR that contain collections of information requirements in the Regulation SBSR Adopting Release.[641] The titles of the collections for Regulation SBSR are: (1) Rule 901—Reporting Obligations—For Reporting Sides; (2) Rule 901—Reporting Obligations—For Registered SDRs; (3) Rule 901—Reporting Obligations—For Platforms; (4) Rule 901—Reporting Obligations—For Registered Clearing Agencies; (5) Rule 901—Reporting Obligations—For New Broker-Dealer Respondents; (6) Rule 902—Public Dissemination of Transaction Reports; (7) Rule 903—Coded Information; (8) Rule 904—Operating Hours of Registered Security-Based Swap Data Repositories; (9) Rule 905—Correction of Errors in Security-Based Swap Information—For Reporting Sides; (10) Rule 905—Correction of Errors in Security-Based Swap Information—For Non-Reporting Sides; (11) Rule 905—Correction of Errors in Security-Based Swap Information—For Registered SDRs; (12) Rule 905—Correction of Errors in Security-Based Swap Information—For Platforms; (13) Rule 905—Correction of Errors in Security-Based Swap Information—For Registered Clearing Agencies; (14) Rule 905—Correction of Errors in Security-Based Swap Information—For New Broker-Dealer Respondents; (15) Rule 906(a)—Other Duties of All Participants—For Registered SDRs; (16) Rule 906(a)—Other Duties of All Participants—For Non-Reporting Sides; (17) Rule 906(b)—Other Duties of All Participants—For All Participants; (18) Rule 906(c)—Other Duties of All Participants—For Covered Participants; (19) Rule 906(c)—Other Duties of All Participants—For Platforms; (20) Rule 906(c)—Other Duties of All Participants—For Registered Clearing Agencies; (21) Rule 906(c)—Other Duties of All Participants—For New Broker-Dealer Respondents; (22) Rule 907—Policies and Procedures of Registered Security-Based Swap Data Repositories; and (23) Rule 908(c)—Substituted Compliance (OMB Control No. 3235–0718). Compliance with these collections of information requirements is mandatory. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the agency displays a currently valid control number.

The Commission is adopting the amendments to Regulation SBSR largely as proposed, with certain revisions. These amendments impact Rules 900, 901, 902, 905, 906, 907, and 908 of Regulation SBSR.

The hours and costs associated with complying with Regulation SBSR constitute reporting and cost burdens imposed by each collection of information. Certain estimates (*e.g.,* the number of reporting sides, the number of non-reporting sides, the number of participants, and the number of reportable events[642] pertaining to security-based swap transactions) contained in the Commission's earlier PRA assessments have been revised to reflect the amendments to Regulation SBSR being adopted today, as well as additional information and data now available to the Commission. The revised paperwork burdens estimated by the Commission herein are consistent with those made in the Regulation SBSR Proposed Amendments Release and the U.S. Activity Proposal. However, as described in more detail below, certain estimates have been modified, as necessary, to reflect the most recent data available to the Commission.

The Commission requested comment on the collection of information requirements associated with the amendments to Regulation SBSR proposed in the Regulation SBSR Proposed Amendments Release and the U.S. Activity Proposal. As noted above, the Commission received 25 comment letters on the Regulation SBSR Proposed Amendments Release and the U.S. Activity Proposal that specifically address Regulation SBSR. Any comments related to the collection of information burdens potentially arising from the proposed amendments are addressed below.

A. Definitions—Rule 900

Rule 900 sets forth definitions of various terms used in Regulation SBSR. In this release, the Commission is adopting certain amendments to Rule 900, including amendments to the definition of "participant" in existing Rule 900(u)[643] and a new defined term "widely accessible" in Rule 900(tt).[644] These changes, in themselves, will not result in any new "collection of information" requirements within the meaning of the PRA. Changes in definitions that might impact a collection of information requirement are considered with the respective rule that imposes the requirement.[645]

Section 29(b) exemption solely to promote legal certainty and to avoid doubt as to the applicability of Section 29(b) to other Exchange Act provisions and that the Commission has "not taken any view as to whether, when, or under what circumstances Section 29(b) might apply to any provision of Title VII of Dodd-Frank or rule or regulation thereunder, including SBSR." ISDA/SIFMA Letter at 18. Because the Commission is not today providing any relief related to the Section 29(b) exemption, the Commission is not modifying the view set forth in the Effective Date Release. *See* Effective Date Release, 76 FR at 36305–306.

[637] 44 U.S.C. 3501 *et seq.*

[638] *See* Regulation SBSR Proposed Amendments Release, 80 FR at 14742–43.

[639] *See* U.S. Activity Proposal, 80 FR at 27503.

[640] 44 U.S.C. 3507; 5 CFR 1320.11.

[641] *See* Regulation SBSR Adopting Release, 80 FR at 14787.

[642] Reportable events include initial security-based swap transactions, life cycle events, and corrections of errors in previously reported information.

[643] Rule 900(u) has been amended such that the definition of "participant" now includes platforms, registered clearing agencies that are required to report alpha dispositions pursuant to new Rule 901(e)(1)(ii), and registered broker-dealers that incur the duty to report security-based swap transactions to a registered SDR pursuant to new Rule 901(a)(2)(ii)(E)(*4*). *See supra* Section V(A).

[644] The adopted definition of "widely accessible" has the effect of prohibiting a registered SDR from charging fees for or imposing usage restrictions on the security-based swap transaction data that it is required to publicly disseminate under Regulation SBSR. *See supra* Section VIII(A).

[645] For example, as a result of the expanded definition of "participant," additional entities now are subject to the requirement in Rule 906(c) to establish, maintain, and enforce written policies and procedures that are reasonably designed to ensure compliance with any obligations to report information to a registered SDR in a manner consistent with Regulation SBSR. *See infra* Section XI(D)(2)(c). The new defined term "widely accessible," however, will not create a new

B. Reporting Obligations—Rule 901

1. Existing Rule 901

Existing Rule 901 specifies, with respect to initial security-based swap transactions and life cycle events (and adjustments due to life cycle events), who is required to report, what data must be reported, when it must be reported, where it must be reported, and how it must be reported. Existing Rule 901(a) sets forth a "reporting hierarchy" that specifies the side that has the duty to report a security-based swap. Existing Rule 901(b) states that if there is no registered SDR that will accept the report required by Rule 901(a), the person required to make the report must report the transaction to the Commission. Existing Rule 901(c) sets forth the primary trade information and Rule 901(d) sets forth the secondary trade information that must be reported. Existing Rule 901(e) requires the reporting of life cycle events and adjustments due to life cycle events. Existing Rule 901(f) requires a registered SDR to timestamp, to the second, any information submitted to it pursuant to Rule 901, and existing Rule 901(g) requires a registered SDR to assign a transaction ID to each security-based swap, or establish or endorse a methodology for transaction IDs to be assigned by third parties. Existing Rule 901(h) requires reporting sides to electronically transmit the information required by Rule 901 in a format required by the registered SDR. Existing Rule 901(i) requires reporting of pre-enactment security-based swaps and transitional security-based swaps to the extent that information about such transactions is available. Existing Rule 901(j) generally provides the person with the duty to report 24 hours from the time of execution to report the required information.

For Reporting Sides. In the Regulation SBSR Adopting Release, the Commission estimated that existing Rule 901 will impose an estimated total first-year burden of approximately 1,394 hours[646] per reporting side for a total first-year burden of 418,200 hours for all reporting sides.[647] The Commission further estimated that existing Rule 901 will impose ongoing annualized aggregate burdens of approximately 687 hours[648] per reporting side for a total aggregate annualized cost of 206,100 hours for all reporting sides.[649] The Commission further estimated that existing Rule 901 will impose initial and ongoing annualized dollar cost burdens of $201,000 per reporting side, for total aggregate initial and ongoing annualized dollar cost burdens of $60,300,000.[650]

For Registered SDRs. In the Regulation SBSR Adopting Release, the Commission estimated that the first-year aggregate annualized burden on registered SDRs associated with existing Rules 901(f) and (g) will be 2,720 burden hours, which corresponds to 272 burden hours per registered SDR.[651] The Commission also estimated that the ongoing aggregate annualized burden associated with existing Rules 901(f) and (g) will be 1,520 burden hours, which corresponds to 152 burden hours per registered SDR.[652]

2. Rule 901—Amendment

The amendments to Rule 901, as adopted herein, establish certain additional requirements relating to the reporting of security-based swap transactions. These amendments contain additional "collection of information requirements" within the meaning of the PRA. The amendments to Rule 901 are contained in three collections: (a) "Rule 901—Reporting Obligations—For New Broker-Dealer Respondents"; (b) "Rule 901—Reporting Obligations—For Platforms"; and (c) "Rule 901—Reporting Obligations—For Registered Clearing Agencies." The following discussion sets forth the additional burdens resulting from the amendments to Rule 901 adopted in this release.

a. Rule 901—Reporting Obligations Resulting From Amendments to Rule 901(a)(2)(ii)(E)

i. Summary of Collection of Information

In the U.S. Activity Proposal, the Commission proposed certain amendments to Rule 901 to assign the duty to report security-based swaps in certain cross-border situations. In this release, the Commission is adopting those amendments as proposed. Under new Rule 901(a)(2)(ii)(E)(*2*), in a transaction between an unregistered U.S. person and an unregistered non-U.S. person who is engaging in ANE activity, the sides are required to select the reporting side. In addition, if both sides are unregistered non-U.S. persons and both are engaging in ANE activity, the sides are required to select the reporting side. New Rule 901(a)(2)(ii)(E)(*3*) addresses the scenario where one side is subject to Rule 908(b) and the other side is not—*i.e.,* one side includes only unregistered non-U.S. persons and that side does not engage in any ANE activity, and the other side includes an unregistered U.S. person or an unregistered non-U.S. person that *is* engaging in ANE activity. Under Rule 901(a)(2)(ii)(E)(*3*), the side with the unregistered U.S. person or the unregistered non-U.S. person engaging in ANE activity is the reporting side. New Rule 901(a)(2)(ii)(E)(*4*) addresses the scenario where neither side includes a counterparty that falls within Rule 908(b)—*i.e.,* neither side includes a registered person, a U.S. person, or a non-U.S. person engaging in ANE activity—but the transaction is effected by or through a registered broker-dealer (including a registered SB SEF). Under Rule 901(a)(2)(ii)(E)(*4*), the registered broker-dealer is required to report the transaction.[653]

ii. Respondents

In the Regulation SBSR Proposed Amendments Release, the Commission estimated that there will be 300 reporting side respondents and that, among the 300 reporting sides,

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collection of information requirement or affect an existing collection of information requirement.

[646] *See* 80 FR at 14676. The Commission derived its estimate from the following: (355 hours (one-time hourly burden for establishing an OMS) + 172 hours (one-time hourly burden for establishing security-based swap reporting mechanisms) + 180 hours (one-time hourly burden for compliance and ongoing support) = 707 hours (one-time total hourly burden). *See* Regulation SBSR Adopting Release, 80 FR at 14676, n. 1074 (436 hours (annual-ongoing hourly burden for internal order management) + 33.3 hours (revised annual-ongoing hourly burden for security-based swap reporting mechanisms) + 218 hours (annual-ongoing hourly burden for compliance and ongoing support) = 687.3 hours (one-time total hourly burden). *See id.* (707 one-time hourly burden + 687 revised annual ongoing hourly burden = 1,394 total first-year hourly burden).

[647] *See* Regulation SBSR Adopting Release, 80 FR at 14676. The Commission derived its estimate from the following: (1,394 hours per reporting side x 300 reporting sides) = 418,200 hours.

[648] *See id.*

[649] *See id.* The Commission derived its estimate from the following: (687 hours per reporting side × 300 reporting sides) = 206,100 hours.

[650] *See id.* The Commission derived its estimate from the following: ($201,000 per reporting side × 300 reporting sides) = $60,300,000. *See* Cross-Border Proposing Release, 78 FR at 31113–15.

[651] *See* Regulation SBSR Adopting Release, 80 FR at 14676. *See* Regulation SBSR Proposing Release, 75 FR at 75250. This figure is based on the following: [(1,200) + (1,520)] = 2,720 burden hours, which corresponds to 272 burden hours per registered SDR.

[652] *See* Regulation SBSR Adopting Release, 80 FR at 14676–77.

[653] In this release, the Commission also is adopting an amendment to Rule 901(d)(9) that requires a registered broker-dealer, if it is required to report a security-based swap under Rule 902(a)(2)(ii)(E)(*4*), to include in the transaction report its broker ID. As discussed in Section XII(A)(6), *infra,* the requirement to identify itself in such a transaction report is considered part of the overall burden of establishing and operating the broker-dealer's reporting infrastructure. As a result, the burdens associated with identifying itself in the transaction report are included in the burdens discussed below. *See infra* notes 916–917 and accompanying discussion.

approximately 50 will likely have to register with the Commission as security-based swap dealers and approximately five will likely have to register as major security-based swap participants, restating an estimate contained in the Regulation SBSR Adopting Release.[654] The Commission noted that these 55 reporting sides likely will account for the vast majority of security-based swap transactions and transaction reports, and that only a limited number of security-based swap transactions would not include at least one of these larger counterparties on either side.[655]

One commenter to the U.S. Activity Proposal recommended that the Commission collect a more complete set of data to more precisely estimate the number of non-U.S. persons that would be affected by the proposed rules.[656] In the U.S. Activity Adopting Release, the Commission stated that, in the absence of comprehensive reporting requirements for security-based swap transactions, and the fact that the location of personnel that arrange, negotiate, or execute a security-based swap transaction is not currently recorded by participants, a more precise estimate of the number of non-U.S. persons affected by the rule is not currently feasible. However, because the Commission assumes that all transactions by foreign dealing entities with other non-U.S. persons on U.S. reference entities are arranged, negotiated, or executed by personnel located in the United States, the analysis contained in the U.S. Activity Adopting Release results in an estimate of the upper bound of the number of firms that would likely assess the location of their dealing activity. The results of such an assessment, already accounted for in the U.S. Activity Adopting Release, determines the number of new respondents impacted by the amendments to Rule 901.

The Commission believes that the amendments to Rule 901(a)(2)(ii)(E), as adopted herein, will result in an additional 20 respondents that will be required to report transactions under the amendments to Regulation SBSR.[657] The Commission estimates that these 20 new respondents will consist solely of registered broker-dealers that are required to report one or more security-based swaps by new Rule 901(a)(2)(ii)(E)(*4*). The Commission acknowledges that amendments to Rule 901(a)(2)(ii)(E) adopted in this release place reporting obligations, in certain circumstances, on unregistered foreign dealing entities, as explained in Section IX(G), *supra,* which may suggest that a larger number of additional respondents is appropriate. However, the Commission notes that, based on observed transaction data in TIW that provided the basis for its estimate of the number of respondents used in the Cross-Border Adopting Release and Regulation SBSR Adopting Release, unregistered foreign dealing entities were already included in the subset of 245 unregistered person respondents that will not be registered security-based swap dealers or major security-based swap participants.[658]

iii. Total Initial and Annual Reporting Burdens

Pursuant to Rule 901, all security-based swap transactions must be reported to a registered SDR or to the Commission. Together, paragraphs (a), (b), (c), (d), (e), (h), and (j) of Rule 901 set forth the parameters that govern how covered transactions are reported. These reporting requirements impose initial and ongoing burdens on respondents. The Commission believes that these burdens will be a function of, among other things, the number of reportable events and the data elements required to be reported for each such event.

Respondents that fall under the reporting hierarchy in Rule 901(a)(2)(ii) incur certain burdens as a result thereof with respect to their reporting of covered transactions. As stated above, the Commission believes that an estimate of 20 additional respondents will incur the duty to report under Regulation SBSR. This estimate includes all persons that will incur a reporting duty under the amendments to Regulation SBSR that are not already subject to burdens under existing Rule 901, as adopted in the Regulation SBSR Adopting Release.

In the Regulation SBSR Adopting Release, the Commission estimated that there will likely be approximately 3 million reportable events per year under Rule 901.[659] The Commission further estimated that approximately 2 million of these reportable events will consist of uncleared transactions. The Commission estimated that 2 million of the 3 million total reportable events will consist of the initial reporting of security-based swaps as well as the reporting of any life cycle events. The Commission also estimated that of the 2 million reportable events, approximately 900,000 will involve the reporting of new security-based swap transactions, and approximately 1,100,000 will involve the reporting of life cycle events under Rule 901(e).[660]

Based on the Commission's assessment of the effect of the amendments to Rule 901(a)(2)(ii)(E) adopted herein, the Commission believes that there will be approximately 2,700 additional reportable events per year under Rule 901.[661] Using a similar approach to the Regulation SBSR Adopting Release,[662] while also accounting for security-based swaps that will be reported by a registered broker-dealer, the Commission estimates that, of the 2,700 new reportable events, 1,512 will involve the reporting of new security-based swap transactions, and approximately 1,188 will involve the reporting of life cycle events under Rule 901(e).[663]

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[654] *See* Regulation SBSR Proposed Amendments Release, 80 FR at 14788.

[655] *See id.*

[656] *See* ISDA I at 7. *See also id.* at 3 (arguing that "the SEC currently lacks the data necessary to precisely estimate . . . the number of registered broker-dealers that intermediate SBS transactions; and the number of additional non-U.S. persons that might incur reporting obligations under the Proposal").

[657] The Commission is unable to determine, at this time, how many of the non-U.S. persons performing the assessments discussed in the U.S. Activity Adopting Release will result in those entities being required to report transactions under Regulation SBSR. The Commission is therefore basing these burdens on the assumption that all entities performing the assessment will be required to report under Regulation SBSR. Further, the 20 respondents here reflect the 30 registered-broker dealers discussed in the U.S. Activity Proposal, reduced by ten to account for registered broker-dealers that are likely also to register as SB SEFs.

[658] The 245 respondents that are unregistered persons are calculated as follows: (300 reporting sides − 50 registered security-based swap dealers − 5 registered major security-based swap participants) = 245 unregistered persons that are reporting sides.

[659] *See* Regulation SBSR Adopting Release, 80 FR at 14675.

[660] The Commission notes that it is adopting an amendment to Rule 901(e)(2). Existing Rule 901(e)(2) states in relevant part that a life cycle event must be reported "to the entity to which the original security-based swap transaction *was reported"* (emphasis added). As amended, Rule 901(e)(2) now states that a life cycle event would have to be reported "to the entity to which the original security-based swap transaction *will be reported or has been reported"* (emphasis added). This amendment accounts for the possibility that persons with a duty to report a transaction generally may do so up to 24 hours after the time of execution, a registered clearing agency might submit a report of a termination of an alpha to the alpha SDR before the alpha SDR has received the transaction report of the alpha transaction itself. *See supra* Section III(I). The Commission does not believe that this amendment to Rule 901(e)(2) gives rise to any PRA burdens not already accounted for in its analysis of burdens under Rule 901. *See infra* Section XI(B)(2)(b).

[661] *See* U.S. Activity Proposal, 80 FR at 27504.

[662] *See* 80 FR at 14676. The Commission notes that, while the approach for determining the burdens is similar to that used in the Regulation SBSR Adopting Release, the aggregate burden hours for all aspects of Rule 901differ slightly as a result of these new respondents having to report a different number of reportable events.

Based on these estimates, the Commission believes that Rule 901(a) will result in the additional new respondents resulting from amendments to Rule 901(a)(2)(ii)(E), having a total burden of 7.6 hours attributable to the initial reporting of security-based swaps by respondents to registered SDRs under Rules 901(c) and 901(d) over the course of a year.[664] The Commission further estimates that these respondents will have a total burden of 5.9 hours attributable to the reporting of life cycle events under Rule 901(e) over the course of a year.[665] Therefore, the Commission believes that the amendments to Rule 901(a)(2)(ii)(E), as adopted herein, will result in a total reporting burden for respondents under Rules 901(c) and (d) along with the reporting of life cycle events under Rule 901(e) of 14 burden hours per year. The Commission believes that many reportable events will be reported through electronic means and that the ratio of electronic reporting to manual reporting is likely to increase over time. The Commission believes that the bulk of the burden hours will be attributable to manually reported transactions.[666] Thus, respondents that capture and report transactions electronically will likely incur fewer burden hours than those respondents that capture and report transactions manually.

Based on the foregoing and applying the same calculation methods used in the Regulation SBSR Adopting Release, the Commission estimates that the amendments to Rule 901 proposed in the U.S. Activity Proposal and adopted herein will impose an estimated total first-year burden of approximately 1,362 hours per respondent[667] for a total first-year burden of 27,240 hours for all additional respondents that will incur the duty to report under the adopted amendments to Rule 901(a)(2)(ii)(E)(*1*)–(*4*).[668] The Commission estimates that the amendments to Rule 901 will impose ongoing annualized aggregate burdens of approximately 655 hours[669] per respondent for a total aggregate annualized burden of 13,100 hours for those respondents.[670] The Commission further estimates that the amendments to Rule 901 will impose initial and ongoing annualized dollar cost burdens of $201,000 per respondent, for total aggregate initial and ongoing annualized dollar cost burdens of $4,020,000.[671]

b. Rule 901—Reporting Obligations for Platforms and Clearing Agencies Resulting From Amendments to Rules 901(a)(1) and (2) and Platforms and Reporting Sides Resulting From Amendments to Rule 901(a)(3)

i. Summary of Collection of Information

In addition to amendments to Rule 901 to assign the duty to report security-based swaps in certain cross-border situations proposed in the U.S. Activity Proposal, in this release the Commission also is assigning the duty to report security-based swaps that are clearing transactions or are executed on a platform and will be submitted to clearing. To facilitate such reporting, the Commission is adopting amendments to Rules 901(a)(1), (a)(2)(i), and (a)(3). Specifically, under new Rule 901(a)(1), if a security-based swap is executed on a platform and will be submitted to clearing, the platform on which the transaction was executed shall have the duty to report the transaction to a registered SDR. New Rule 901(a)(2)(i) assigns the reporting duty for a clearing transaction to the registered clearing agency that is a counterparty to the security-based swap. New Rule 901(a)(3) requires any person that has a duty to report a security-based swap that is submitted to clearing—which would be a platform or a reporting side—to provide the registered clearing agency with the transaction ID of the alpha and the identity of the registered SDR to which the alpha will be reported or has been reported.

ii. Respondents

The amendments to Rules 901(a)(1) and (a)(2)(i) adopted herein assign reporting duties for security-based swap transactions, in certain enumerated cases set forth in these rules, to platforms and registered clearing agencies, respectively. The Commission estimates that these amendments to Rule 901(a) will result in 14 additional respondents incurring the duty to report under Regulation SBSR: Ten platforms and four registered clearing agencies.[672] Amended Rule 901(a)(3) will require a person—either the platform upon which the security-based swap was executed or the reporting side for those security-based swaps other than clearing transactions—to report, for those security-bases swaps submitted to a registered clearing agency, the transaction ID of the submitted security-based swap and the identity of the registered SDR to which the transaction will be or has been reported. The Commission believes that new Rule 901(a)(3), as amended, will place reporting obligations on 300 reporting sides[673] and ten platforms.[674]

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[663] *See* U.S. Activity Proposal, 80 FR at 27504. The Commission expects 540 reportable events (2,700 × 0.2) to be new security-based swap transactions reported by registered broker-dealers, and 972 reportable events to be other new security-based swap transactions that would be required to be reported under the rule ((2,700 − 540) × 0.45), for a total of 1,512 reportable events that are new security-based swap transactions. The remaining 1,188 reportable events ((2,700 − 540) × 0.55) are estimated to be life cycle events reportable under Rule 901(e).

[664] The Commission calculated the following: ((1,512 × 0.005)/(20 respondents)) = 0.38 burden hours per respondent or 7.6 total burden hours attributable to the initial reporting of security-based swaps. *See* U.S. Activity Proposal, 80 FR at 27505 (adjusted to reflect revised number of respondents). In the Regulation SBSR Adopting Release, the Commission estimated that it would take approximately 0.005 hours for each security-based swap transaction to be reported. *See* 80 FR at 14676, n. 1073. *See also* Regulation SBSR Proposing Release, 75 FR at 75249, n. 195.

[665] The Commission calculated the following: ((1,188 × 0.005)/(20 respondents)) = 0.30 burden hours per reporting side or 5.9 total burden hours attributable to the reporting of life cycle events under Rule 901(e). *See* U.S. Activity Proposal, 80 FR at 27505 (adjusted to reflect revised number of respondents). In the Regulation SBSR Adopting Release, the Commission estimated that it would take approximately 0.005 hours for each security-based swap transaction to be reported. *See* 80 FR 14676, n. 1073. *See also* Regulation SBSR Proposing Release, 75 FR at 75249, n. 195.

[666] *See* Regulation SBSR Adopting Release, 80 FR at 14676.

[667] The Commission derived its estimate from the following: (355 hours (one-time hourly burden for establishing an OMS) + 172 hours (one-time hourly burden for establishing security-based swap reporting mechanisms) + 180 hours (one-time hourly burden for compliance and ongoing support) = 707 hours (one-time total hourly burden). *See* U.S. Activity Proposal, 80 FR at 27505, n. 454 (436 hours (annual ongoing hourly burden for internal order management) + 0.68 hours (revised annual ongoing hourly burden for security-based swap reporting mechanisms as a result of reduced estimate of number of respondents) + 218 hours (annual-ongoing hourly burden for compliance and ongoing support) = 654.7 hours (one-time total hourly burden). *See* U.S. Activity Proposal, 80 FR at 27505, n. 454 (revised to take into account reduced estimate of number of respondents) (707 one-time hourly burden + 654.7 revised annual-ongoing hourly burden = 1,362 total first-year hourly burden).

[668] The Commission derived its estimate from the following: (1,362 hours per respondent × 20 respondents) = 27,240 hours.

[669] *See supra* note 667.

[670] The Commission derived its estimate from the following: (655 hours per respondent × 20 respondents) = 13,100 hours.

[671] The Commission derived its estimate from the following: ($201,000 per respondent × 20 respondents) = $4,020,000. *See* U.S. Activity Release, 80 FR at 27505 (providing preliminary estimates based on a higher number of respondents). *See also* Regulation SBSR Adopting Release, 80 FR at 14676, nn. 1066 and 1078.

[672] The Commission made the same preliminary estimate of the number of respondents resulting from these proposed amendments in the Regulation SBSR Proposed Amendments Release. *See* 80 FR at 14788.

iii. Total Initial and Annual Reporting Burdens

(a) Platforms and Registered Clearing Agencies

Pursuant to Rule 901, all security-based swap transactions must be reported to a registered SDR or to the Commission. Together, paragraphs (a), (b), (c), (d), (e), (h), and (j) of Rule 901 set forth the parameters that reporting entities must follow to report security-based swap transactions. Because platforms and registered clearing agencies now have the duty to report, initial and ongoing burdens will be placed on these entities. The Commission continues to believe that these burdens will be a function of, among other things, the number of reportable events and the data elements required to be reported for each such event.

In the Regulation SBSR Adopting Release, the Commission estimated that respondents will face three categories of burdens to comply with Rule 901.[675] The Commission believes that platforms and registered clearing agencies will face the same categories of burdens as those identified in the Regulation SBSR Adopting Release for other types of respondents. First, each platform and registered clearing agency will likely have to develop the ability to capture the relevant transaction information.[676] Second, each platform and registered clearing agency will have to implement a reporting mechanism. Third, each platform and registered clearing agency will have to establish an appropriate compliance program and support for the operation of any system related to the capture and reporting of transaction information. The Commission continues to believe that platforms and registered clearing agencies will need to develop capabilities similar to those highlighted in the Regulation SBSR Adopting Release in order to be able to capture and report security-based swap transactions. The Commission also continues to believe that, once a platform or registered clearing agency's reporting infrastructure and compliance systems are in place, the burden of reporting each individual reportable event will be small when compared to the burdens of establishing the reporting infrastructure and compliance systems.[677] The Commission continues to believe that all of the reportable events, for which platforms and registered clearing agencies will be responsible for reporting, will be reported through electronic means.[678]

In the Regulation SBSR Adopting Release, the Commission estimated that the total burden placed upon reporting sides as a result of existing Rule 901 will be approximately 1,361 hours[679] per reporting side during the first year,[680] before taking into account the reporting of individual reportable events. The Commission believes that the per-entity cost will be comparable for platforms and registered clearing agencies, resulting in a total first-year burden of 1,361 hours and an annual burden of 654 hours for each platform and registered clearing agency, before taking into account the reporting of individual reportable events, under new Rules 901(a)(1) and (a)(2)(i), as adopted herein.

In the Regulation SBSR Adopting Release, the Commission estimated that there will be approximately 3 million reportable events per year under Rule 901, of which approximately 2 million will consist of uncleared transactions (*i.e.,* those transactions that will be reported by a reporting side).[681] In the Regulation SBSR Adopting Release, the Commission did not assign reporting duties for the remaining 1 million annual reportable events, which consist of platform-executed alphas, clearing transactions, and any life cycle events pertaining to these two types of transactions.

In this release, the Commission is adopting amendments to Rule 901 that assign the reporting duty for these 1 million reportable events to platforms and registered clearing agencies. The Commission estimates that, of the 1 million reportable events, approximately 370,000 will be new security-based swap transactions.[682] Of these 370,000 new transactions, the Commission estimates that platforms will be responsible for reporting approximately one-third, or 120,000, of them.[683] The Commission estimates that the amendments to Rule 901(a) will result in platforms having a total burden of 600 hours attributable to the reporting of security-based swaps under Rule 901 over the course of a year, or 60 hours per platform.[684]

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[673] As stated above, the Commission has estimated that there would be 300 reporting sides plus the 20 new broker-dealer respondents discussed in Section XI(B)(2)(a), *supra. See also supra* note 657.

[674] Although new Rule 901(a)(2)(ii)(E)(*4*) requires a registered broker-dealer to report security-based swaps in some circumstances, the Commission believes that registered broker-dealers will not incur duties under Rule 901(a)(3). A registered broker-dealer would incur the reporting duty only if it effects a transaction for unregistered non-U.S. counterparties, neither of which is engaging in ANE activity. If the unregistered non-U.S. direct counterparties have guarantors that would clear the transaction on their behalf, it is likely that one or both of these guarantors would occupy a higher rung on the reporting hierarchy such that the duty would not fall to the registered broker-dealer under Rule 901(a)(2)(ii)(E)(*4*). Therefore, it is unlikely that a broker-dealer that effects such a transaction would incur the duty under Rule 901(a)(3) to provide the transaction ID and the identity of the alpha SDR to the registered clearing agency.

[675] *See* Regulation SBSR Adopting Release, 80 FR at 14675–77.

[676] In the Regulation SBSR Adopting Release, the Commission discussed the development, by reporting sides, of an internal order and trade management system. *See* 80 FR at 14675–76. The Commission continues to believe that the costs of developing a transaction processing system are comparable to the costs discussed therein. Although the actual reporting infrastructure needed by platforms and registered clearing agencies could have some attributes that differ from the attributes of an internal order and trade management system, the Commission nonetheless believes that the cost of implementing a transaction processing system, and establishing an appropriate compliance program and support for the operation of the system, will be similar to the costs for reporting sides discussed in the Regulation SBSR Adopting Release.

[677] In the Regulation SBSR Adopting Release, the Commission reiterated its belief that reporting specific security-based swap transactions to a registered SDR—separate from the establishing of infrastructure and compliance systems that support reporting—will impose an annual aggregate cost of approximately $5,400,000. *See* 80 FR at 14675–77.

[678] As a result of the amendment to Rule 901(h) adopted herein, which replaces "reporting side" with "person having the duty to report," all persons who have a duty to report under Regulation SBSR must electronically transmit the information required by Rule 901 in a format required by the registered SDR. The Commission believes that the infrastructure build described above will necessarily include the ability to electronically transmit to a registered SDR the information required by Rule 901, such that any burdens resulting from the amendment to Rule 901(h) are included within the Rule 901 burdens for persons with the duty to report that are not reporting sides.

[679] The Commission derived its estimate from the following: (355 hours (one-time hourly burden for establishing an OMS) + 172 hours (one-time hourly burden for establishing security-based swap reporting mechanisms) + 180 hours (one-time hourly burden for compliance and ongoing support) = 707 hours (one-time total hourly burden). *See* Regulation SBSR Proposed Amendments Release, 80 FR at 14789, n. 298 (436 hours (annual ongoing hourly burden for internal order management) + 218 hours (annual-ongoing hourly burden for compliance and ongoing support) = 654 hours (one-time total hourly burden. *See id.* (707 one-time hourly burden + 654 revised annual-ongoing hourly burden = 1,361 total first-year hourly burden).

[680] *See* Regulation SBSR Adopting Release, 80 FR at 14675–77.

[681] *See id.*

[682] *See* Regulation SBSR Amendments Proposing Release, 80 FR at 14777, n. 235.

[683] Since only platform-executed security-based swaps that will be submitted to a registered clearing agency for clearing are subject to this release, platforms are not responsible for any life cycle event reporting under Rule 901(e). *See* Regulation SBSR Amendments Proposing Release, 80 FR at 14777.

[684] The Commission calculates the following: ((120,000 × 0.005)/(10 platforms)) = 60 burden hours per platform or 600 total burden hours attributable to the reporting of security-based swaps. *See* Regulation SBSR Proposed

The Commission estimates that registered clearing agencies will be responsible for reporting 880,000 reportable events.[685] These reportable events consist of 250,000 initial security-based swaps along with 630,000 life cycle events. The Commission estimates that the amendments to Rule 901(a) will result in registered clearing agencies having a total burden of 1,250 hours attributable to the reporting of new security-based swaps to registered SDRs over the course of a year, or 312.5 hours per registered clearing agency.[686] The Commission estimates that the amendments to Rule 901(a) will result in registered clearing agencies having a total burden of 3,150 hours attributable to the reporting of life cycle events to registered SDRs under Rule 901(e) over the course of a year, or 787.5 hours per registered clearing agency.[687] The Commission continues to believe that the amendments will result in a total reporting burden for registered clearing agencies under Rules 901(c) and 901(d) along with the reporting of life cycle events under Rule 901(e) of 4,400 burden hours, or 1,100 hours per registered clearing agency.[688] The Commission believes that all reportable events that will be reported by platforms and registered clearing agencies pursuant to these amendments will be reported through electronic means.

The Commission estimates that the amendments to Rule 901 will impose ongoing annualized aggregate burdens of approximately 714 hours per platform[689] for a total aggregate annualized burden of 7,140 hours for all platforms.[690] The Commission further believes that the first year burden on platforms will be 1,421 burden hours per platform[691] for a total first year burden of 14,210 burden hours for all platforms.[692] The Commission further estimates that the amendments to Rule 901 will impose initial and ongoing annualized dollar cost burdens of $201,000 per platform,[693] for total aggregate initial and ongoing annualized dollar cost burden of $2,010,000.[694]

The Commission estimates that the amendments to Rule 901 will impose ongoing annualized aggregate burdens of approximately 1,754 hours per registered clearing agency[695] for a total aggregate annualized burden of 7,016 hours for all registered clearing agencies.[696] The Commission further believes that the first year burden on registered clearing agencies will be 2,461 burden hours per registered clearing agency[697] for a total first year burden of 9,844 burden hours for all registered clearing agencies.[698] The Commission further estimates that the amendments to Rule 901 will impose initial and ongoing annualized dollar cost burdens of $401,000 per registered clearing agency,[699] for total aggregate initial and ongoing annualized dollar cost burden of $1,604,000.[700]

The Commission recognizes that some entities that will qualify as platforms or registered clearing agencies may have already spent time and resources building the infrastructure that will support their eventual reporting of security-based swaps. The Commission notes that, as a result, the burdens and costs estimated herein could be greater than those actually incurred by affected parties as a result of compliance with the amendments to Rule 901(a). Nonetheless, the Commission believes that its estimates represent a reasonable approach to estimating the paperwork burdens associated with the amendments to Rule 901(a).

(b) Rule 901(a)(3) Burdens

Rule 901(a)(3), as adopted herein, requires a person who has the duty to report an alpha security-based swap to promptly provide the registered clearing agency to which the alpha has been submitted the transaction ID of the submitted security-based swap and the identity of the registered SDR to which the transaction will be or has been

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Amendments Release, 80 FR at 14789–90. In the Regulation SBSR Proposing Release, the Commission estimated that it would take approximately 0.005 hours for each security-based swap transaction to be reported. *See* 75 FR at 75249, n. 195.

[685] As is discussed above, the Commission estimates that platforms will be responsible for reporting only approximately 120,000 of the 1 million new reportable events and registered clearing agencies will be responsible for reporting the remainder.

[686] The Commission calculates the following: ((250,000 security-based swaps × 0.005 hours per security-based swap)/(4 registered clearing agencies)) = 312.5 burden hours per registered clearing agency or 1,250 total burden hours attributable to the reporting of such security-based swaps. *See* Regulation SBSR Proposed Amendments Release, 80 FR at 14789–90. In the Regulation SBSR Proposing Release, the Commission estimated that it would take approximately 0.005 hours for each security-based swap to be reported. *See* 75 FR at 75249, n. 195.

[687] The Commission calculates the following: ((630,000 security-based swaps × 0.005 hours per security-based swap)/(4 registered clearing agencies)) = 787.5 burden hours per registered clearing agency or 3,150 total burden hours attributable to the reporting of life cycle events under Rule 901(e). *See* Regulation SBSR Proposed Amendments Release, 80 FR at 14789–90. In the Regulation SBSR Proposing Release, the Commission estimated that it would take approximately 0.005 hours for each security-based swap to be reported. *See* 75 FR at 75249, n. 195.

[688] As is discussed immediately above, the Commission believes that registered clearing agencies would incur a burden of 1,250 hours attributable to the reporting of security-based swaps pursuant to Rule 901(a)(2)(i) along with a burden of 3,150 hours attributable to the reporting of life cycle events under Rule 901(e). As discussed in note 683, *supra*, a platform is not responsible for the reporting of any life cycle events of any platform-executed security-based swap that will be submitted to clearing.

[689] As discussed above, the Commission believes that platforms will incur a burden of 654 hours per year (before taking into account individual transaction reporting) plus a transaction reporting burden of 60 hours per year resulting in a total annual burden per platform of 714 burden hours.

[690] The Commission derived its estimate from the following: (714 hours per platform × 10 platforms) = 7,140 hours.

[691] As discussed above, the Commission believes that platforms will incur an initial burden of 707 hours plus an annual burden of 714 hours for a total burden of 1,421 per platform.

[692] The Commission derived its estimate from the following: (1,421 hours per platform × 10 platforms) = 14,210 hours.

[693] *See* Regulation SBSR Proposed Amendments Release, 80 FR at 14789, n. 303 (these burdens reflect the dollar costs of hardware and software related expenses, including necessary back-up and redundancy, per SDR connection, for two SDR connections, along with cost of storage capacity, reduced to account only for platforms).

[694] The Commission derived its estimate from the following: ($201,000 per reporting person × 10 platforms) = $2,010,000.

[695] As discussed above, the Commission believes that registered clearing agencies will incur a burden of 654 hours per year (before taking into account individual transaction reporting) plus a transaction reporting burden of 1,100 hours per year resulting in a total annual burden of 1,754 burden hours.

[696] The Commission derived its estimate from the following: (1,754 hours per registered clearing agency × 4 registered clearing agencies) = 7,016 hours.

[697] As discussed above, the Commission believes that platforms will incur an initial burden of 707 hours plus an annual burden of 1,754 hours for a total burden of 2,461 per registered clearing agency.

[698] The Commission derived its estimate from the following: (2,461 hours per registered clearing agency × 4 registered clearing agencies) = 9,844 hours.

[699] *See* Regulation SBSR Proposed Amendments Release, 80 FR at 14789, n. 303 (reduced to account only for registered clearing agencies). The Commission estimates that a registered clearing agency, as a result of newly adopted Rule 901(e)(1)(ii), might have to establish connectivity to an alpha SDR, to which it might not otherwise establish connectivity. Accordingly, the Commission estimates that each registered clearing agency will connect to four registered SDRs. The Commission derived the total estimated expense for registered clearing agencies as (($100,000 hardware- and software-related expenses, including necessary backup and redundancy, per SDR connection) × (4 SDR connections per registered clearing agency)) + ($1,000 cost of storage capacity) = $401,000 per registered clearing agency. *See* Regulation SBSR Proposed Amendments Release, 80 FR at 14776 (estimating the hardware- and software-related expenses per SDR connection at $100,000). This estimate assumes that the systems required to establish connectivity to a registered SDR to meet requirements under Rule 901(e)(1)(ii) are similar to those required by reporting sides to meet regulatory reporting requirements. To the extent that a registered clearing agency is able to utilize a limited purpose connection to report only the information required by Rule 901(e)(1)(ii), the cost of establishing such a connection could be less.

[700] The Commission derived its estimate from the following: ($401,000 per registered clearing agency × 4 registered clearing agencies) = $1,604,000.

reported. Entities that report alphas to registered SDRs also will already have established the infrastructure needed to submit security-based swaps to a registered clearing agency that acts as a central counterparty; this connectivity to a registered clearing agency is not required by Regulation SBSR. Rule 901(a)(3) will require the person who reports the alpha to a registered SDR to provide the registered clearing agency two additional data elements—the transaction ID of the alpha and the identity of the alpha SDR—along with all of the other transaction information that must be submitted to clear the transaction. The Commission estimates that the additional one-time burden related to the development of the ability to capture and submit these two additional data elements will be 10 burden hours per respondent and the additional one-time burden related to the implementation of a reporting mechanism will be 6 burden hours per respondent.[701] The Commission estimates that the additional ongoing burden related to the ability to capture the additional specific data elements required by amended Rule 901(a)(3) will be 10 burden hours and the additional ongoing burden related to the maintenance of the reporting mechanism will be 2 burden hours, per platform and reporting side.[702]

(c) Bunched Order Executions and Allocations

Bunched order executions and the security-based swaps that result from their allocation are types of security-based swaps that must be reported pursuant to Rule 901(a). In the Regulation SBSR Adopting Release, the Commission provided guidance regarding how Regulation SBSR applies to uncleared bunched order executions and the security-based swaps that result from their allocation.[703] In Section VI, *supra,* the Commission provides guidance regarding how Regulation SBSR applies to bunched order executions that will be submitted to clearing and the security-based swaps that result from the allocation of any bunched order execution, if the resulting security-based swaps are cleared.

This guidance does not increase the number of respondents under Regulation SBSR or increase the burdens for any respondent.[704] The estimates of the number of reportable events provided by the Commission in the Regulation SBSR Adopting Release included bunched order executions and the security-based swaps that result from their allocation. Thus, there are no burdens associated with this guidance that the Commission has not already taken into account.

(d) Prime Brokerage Transactions

In the Regulation SBSR Proposed Amendments Release, the Commission set forth the application of Regulation SBSR to a prime brokerage transaction involving three security-based swap legs. In Section VII(B)(2), *supra,* the Commission supplements its views to account for cases where the documentation among the relevant market participants provides for a two-legged structure rather than a three-legged structure. Since the Commission's initial estimates of the number of reportable events provided for the reporting of all legs of a prime brokerage transaction,[705] those estimates assumed that prime brokerage transactions involved a three-legged structure. In light of the possibility that some prime brokerage transactions may involve only two legs, the Commission may have overestimated the total number of reportable events arising from prime brokerage transactions. However, because prime brokerage transactions are unlikely to represent a significant percentage of reportable events, the Commission continues to believe that its previous estimate of reportable events is reasonable.[706]

3. Rule 901—Aggregate Total PRA Burdens and Costs

Based on the foregoing, the Commission estimates the following aggregate total PRA burdens and costs, by category of entity, resulting from Rule 901, as contained in the Regulation SBSR Adopting Release and as amended in this release.

a. For Platforms

As discussed in Section XI(B)(2)(b)(iii)(a), *supra,* the Commission estimates that the hourly burden resulting from the amendments to Rule 901(a)(1) on platforms would be 1,421 hours in the first year and 714 hours annually thereafter, per platform. The Commission further estimates that the annual dollar cost of the amendments will be $201,000. The Commission also estimates that the hourly burden resulting from the amendments to Rule 901(a)(3) on platforms will be 28 hours in the first year and 12 hours annually thereafter, per platform. In aggregate, the Commission estimates that the amendments to Rule 901 will result in a first year burden 1,449 hours per platform for a total first year hourly burden of 14,490 hours. The Commission further estimates that the annual aggregate burden resulting from the amendments to Rule 901 will be 726 hours per platform, for a total annual hourly burden of 7,260 hours. Finally, the Commission estimates that the annual dollar cost of the amendments will be $201,000 per platform, for a total annual dollar cost of $2,010,000.

b. For Registered Clearing Agencies

As discussed in Section XI(B)(2)(b)(iii)(a), *supra,* the Commission estimates that the hourly burden resulting from the amendments to Rule 901(a)(2) on registered clearing agencies will be 2,461 hours in the first year and 1,754 hours annually thereafter, per registered clearing agency. The Commission estimates that the total hourly burden on all registered clearing agencies will be 9,844 in the first year and 7,016 annually thereafter. The Commission further estimates that the annual dollar cost of the amendments will be $401,000 per registered clearing agency, or $1,604,000 for all registered clearing agencies.

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[701] The Commission estimates that the additional burdens related to programming systems to allow for the reporting of the additional data fields will be: [(Sr. Programmer (5 hours) + Sr. Systems Analyst (5 hours)) = 10 burden hours (development of the ability to capture transaction information); (Sr. Programmer (3 hours) + Sr. Systems Analyst (3 hours)) = 6 burden hours (implementation of reporting mechanism)]. The total one-time burden associated with Rule 901(a)(3) will be 16 burden hours per respondent for a total one-time burden of 4,960 hours (16 × 310 (*i.e.,* 300 reporting sides + 10 platforms)). *See* Regulation SBSR Proposed Amendments Release, 80 FR at 14790, n. 315.

[702] The Commission estimates that the additional burdens related to the reporting of these additional data fields will be: [(Sr. Programmer (5 hours) + Sr. Systems Analyst (5 hours)) = 10 burden hours (maintenance of transaction capture system); (Sr. Programmer (1 hour) + Sr. Systems Analyst (1 hour)) = 2 burden hours (maintenance of reporting mechanism)]. The total ongoing burden associated with amended Rule 901(a) will be 12 burden hours per platform and reporting side for a total ongoing burden of 3,720 hours (12 × 310 (*i.e.,* 300 reporting sides + 10 platforms)). For the Commission's preliminary estimate of the burdens associated with Rule 901(a)(3), *see* Regulation SBSR Proposed Amendments Release, 80 FR at 14790, n. 316.

[703] *See* 80 FR at 14626–27.

[704] For the Commission's preliminary estimate of the burdens associated with this guidance, *see* Regulation SBSR Proposed Amendments Release, 80 FR at 14790.

[705] *See* Regulation SBSR Proposed Amendments Release, 80 FR at 14785, n. 276.

[706] Combining the Commission's estimates in the Regulation SBSR Adopting Release and this release, the Commission believes that there will be approximately 3 million reportable events per year under Rules 901 and 905. Two million of those reportable events were required to be reported pursuant to provisions adopted in the Regulation SBSR Adopting Release, and 1 million are required to be reported by amendments adopted herein. *See supra* Section XI(B)(2)(a)(iv).

c. For New Broker-Dealer Respondents

The Commission believes that, as a result of amendments to Rule 901(a)(2)(ii)(E) adopted herein, there will be 20 new broker-dealer respondents who will incur reporting responsibilities, and that they will incur first-year burdens of 1,362 hours. The Commission further believes that these new respondents will incur annual burdens of 655 hours each year thereafter. In addition, the Commission believes that these new respondents will incur annual costs of $201,000.

d. For Reporting Sides

In the Regulation SBSR Adopting Release, the Commission estimated that reporting sides will incur a first-year burden of 1,394 hours per reporting side and an hourly burden of 687 hours annually thereafter.[707] As a result of the amendments to Rule 901(a)(3) adopted herein, the Commission believes that these burdens will increase. The Commission believes that reporting sides will have a new first-year burden of 1,422 hours per reporting side,[708] or 426,600 hours for all reporting sides.[709] The Commission further estimates that reporting sides will have a new annual burden after the first year of 699 hours per reporting side,[710] or 209,700 hours for all reporting sides.[711] The Commission also believes that the annual dollar cost of Rule 901 to reporting sides will remain unchanged at $201,000 per reporting side, or $60,300,000 for all reporting sides.

C. Correction of Errors in Security-Based Swap Information—Rule 905

1. Existing Rule 905

Existing Rule 905 sets out a process for correcting errors in reported and disseminated security-based swap information. Under Rule 905(a)(1), where a counterparty that was not on the reporting side for a security-based swap transaction discovers an error in the information reported with respect to such security-based swap, that counterparty must promptly notify the reporting side of the error. Under existing Rule 905(a)(2), where a reporting side for a security-based swap transaction discovers an error in the information reported with respect to a security-based swap, or receives notification from its counterparty of an error, the reporting side must promptly submit to the entity to which the security-based swap was originally reported an amended report pertaining to the original transaction. An amended report must be submitted to a registered SDR in a manner consistent with the policies and procedures of the registered SDR required pursuant to Rule 907(a)(3).

Existing Rule 905(b) sets forth the duties of a registered SDR relating to corrections. If the registered SDR either discovers an error in a transaction on its system or receives notice of an error from a reporting side, the registered SDR must verify the accuracy of the terms of the security-based swap and, following such verification, promptly correct the erroneous information contained in its system. Rule 905(b)(2) further requires that, if such erroneous information relates to a security-based swap that the registered SDR previously disseminated and falls into any of the categories of information enumerated in Rule 901(c), the registered SDR must publicly disseminate a corrected transaction report of the security-based swap promptly following verification of the trade by the counterparties, with an indication that the report relates to a previously disseminated transaction.

In the Regulation SBSR Adopting Release, the Commission estimated that Rule 905(a) will impose an initial, one-time burden associated with designing and building a reporting side's reporting system to be capable of submitting amended security-based swap transactions to a registered SDR. The Commission further estimated that Rule 905(a) will impose on all reporting sides an initial (first-year) aggregate burden of 15,015 hours, which is 50.0 burden hours per reporting side,[712] and an ongoing aggregate annualized burden of 7,035 hours, which is 23.5 burden hours per reporting side.[713]

With regard to non-reporting-side participants, the Commission estimated in the Regulation SBSR Adopting Release that Rule 905(a) will impose an initial and ongoing burden associated with promptly notifying the reporting side after discovery of an error as required under Rule 905(a)(1).[714] The Commission estimated that the annual burden will be 998,640 hours, which corresponds to 208.05 burden hours per non-reporting-side participant.[715]

Existing Rule 905(b) requires a registered SDR to develop protocols regarding the reporting and correction of erroneous information. In the Regulation SBSR Adopting Release, the Commission noted that the rules adopted in the SDR Adopting Release generally require a registered SDR to have the ability to collect and maintain security-based swap transaction reports and update relevant records and, in light of these broader duties, that the burdens imposed by Rule 905(b) on a registered SDR will represent only a minor extension of these main duties.[716] The Commission also stated that a registered SDR must have the capacity to disseminate additional, corrected security-based swap transaction reports pursuant to Rule 902. The Commission concluded that the burdens on registered SDRs associated with Rule 905—including systems development, support, and maintenance—are addressed in the Commission's analysis of those other rules and, thus, that Rule 905(b) imposes only an incremental additional burden on registered SDRs.[717]

The Commission estimated in the Regulation SBSR Adopting Release that the initial (first-year) aggregate annualized burden on registered SDRs under Rule 905 will be 21,900 burden hours, which corresponds to 2,190 burden hours for each registered SDR.[718] The Commission further estimated that the ongoing aggregate annualized burden on registered SDRs under Rule 905 will be 14,600 burden hours, which corresponds to 1,460 burden hours for each registered SDR.[719]

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[707] *See* Regulation SBSR Adopting Release, 80 FR at 14676.

[708] The Commission estimates the new first year burden as follows: (1,394 hours (original burden resulting from previously adopted rules) + 28 hours (burden resulting from amendments to Rule 901(a)(3))) = 1,422 hours.

[709] The Commission estimates the new aggregate burden as follows: (1,422 hours × 300 reporting sides) = 426,600 hours.

[710] The Commission estimates the new annual burden as follows: (687 hours (original burden resulting from previously adopted rules) + 12 hours (burden resulting from amendments to Rule 901(a)(3))) = 699 hours.

[711] The Commission estimates the new aggregate burden as follows: (699 hours × 300 reporting sides) = 209,700 hours.

[712] *See* Regulation SBSR Adopting Release, 80 FR at 14681–83.

[713] *See id.*

[714] *See id.*

[715] This figure was based on the Commission's estimate of (1) 4,800 non-reporting-side participants; and (2) one transaction per day per non-reporting-side participant. The Commission noted that the burdens of Rule 905 on reporting sides and non-reporting-side participants will be reduced to the extent that complete and accurate information is reported to registered SDRs in the first instance pursuant to Rule 901. *See id.*

[716] *See id.*

[717] The Commission estimated that developing and publicly providing the necessary procedures will impose on each registered SDR an initial one-time burden of approximately 730 burden hours, and that to review and update such procedures on an ongoing basis will impose an annual burden on each registered SDR of approximately 1,460 burden hours. *See id.*

[718] *See id.* at 14682, n. 1130–32.

[719] *See id.*, nn. 1131, 1133.

2. Amendments to Rule 905

In this release, the Commission is adopting amendments to Rule 905 that broaden the scope and increase the number of respondents that will incur duties under the rule. These amendments will not increase the number of registered SDRs that are respondents to the rule or increase the burdens on SDRs.

Certain provisions of Rule 905 of Regulation SBSR contain "collection of information requirements" within the meaning of the PRA. The title of these collections are: (a) "Rule 905—Correction of Errors in Security-Based Swap Information—For New Broker-Dealer Respondents"; (b) "Rule 901—Correction of Errors in Security-Based Swap Information—For Platforms"; and (c) "Rule 901— Correction of Errors in Security-Based Swap Information—For Registered Clearing Agencies."

a. Summary of Collection of Information

Rule 905, as adopted in the Regulation SBSR Adopting Release, imposes duties on: (1) Non-reporting sides, to inform the reporting side if the non-reporting side discovers an error; (2) reporting sides, to correct the original transaction report if the reporting side discovers an error or is notified of an error by the non-reporting side; and (3) registered SDRs, upon discovery of an error or receipt of a notice of an error, to verify the accuracy of the terms of the security-based swap and, following such verification, correcting the record and, if necessary, publicly disseminating a corrected transaction report. The amendments to Rule 905, as adopted herein, do not alter the basic duties under Rule 905 but instead are designed to account for the fact that a person other than a side might, under other amendments adopted herein, have the duty to report the initial transaction. Thus, Rule 905, as amended herein, requires non-reporting sides to notify "the person having the duty to report the security-based swap" of the error (not "the reporting side"), and "the person having the duty to report the security-based swap" (not "the reporting side") must correct the original transaction report if such person discovers an error or is notified of an error by a non-reporting side.

The amendments to Rule 905 adopted herein do not alter the nature of the duties incurred by registered SDRs. However, amendments to other parts of Regulation SBSR adopted herein will increase the number of security-based swap transactions that must be reported to a registered SDR. Because the Commission assumes that some number of those transactions will be reported with errors and will have to be corrected pursuant to Rule 905, these other amendments will indirectly increase the burdens imposed on registered SDRs by Rule 905(b), because registered SDRs will have to correct the records for more transactions (and, in appropriate cases, disseminate more corrected transaction reports). These amendments also will increase the number of non-reporting sides and "persons having the duty to report the security-based swap" who will incur duties under Rule 905(a).

b. Respondents

The Commission previously estimated that Rule 905, as adopted in the Regulation SBSR Adopting Release, will have the following respondents: 300 reporting sides that incur the duty to report security-based swap transactions pursuant to existing Rule 901 and thus might incur duties to submit error corrections to registered SDRs under Rule 905(a)(2); up to 4,800 participants of one or more SDRs (or non-reporting sides) that might incur duties under Rule 905(a)(1); and ten registered SDRs that might incur duties under Rule 905(b).[720]

As a result of various amendments being adopted today, the Commission estimates that ten platforms, four registered clearing agencies, and 20 new broker-dealers respondents (exclusive of SB SEFs) also will incur duties under Rule 905(a)(2), because these entities will incur the duty to report initial transactions and thus will likely have to report some error corrections. The Commission's estimates of the number of reporting sides (300), non-reporting sides (4,800), and registered SDRs (10) that will be respondents of Rule 905 remain unchanged. However, the Commission now believes that four registered clearing agencies, ten platforms, and 20 new broker-dealer respondents will also like have to report some error corrections.

c. Total Initial and Annual Reporting Burdens

i. New Broker-Dealer Respondents

In the U.S. Activity Proposal, the Commission preliminarily estimated that the incremental burden imposed on registered broker-dealers to comply with the error reporting requirements of Rule 905 would be equal to 5% of the one-time and annual burdens associated with designing and building the reporting infrastructure necessary for reporting transactions under Rule 901, plus 10% of the corresponding one-time and annual burdens associated with developing the reporting side's overall compliance program required under Rule 901.[721] The Commission preliminarily estimated that the new broker-dealer respondents would incur, as a result of Rule 905(a), an initial (first-year) burden of 48.4 burden hours per respondent, and an ongoing annual burden of 21.8 burden hours. Based on additional information available to the Commission, the Commission now estimates that, as a result of amendments to Rule 901(a)(2)(ii)(E), there will be only 20 new broker-dealer respondents who will be required to report transactions and other reportable events. These new broker-dealer respondents will have error correction duties similar to reporting sides; the Commission believes, therefore, that respondent broker-dealers will incur burdens similar to reporting sides under Rule 905(a). The Commission estimates that these 20 new broker-dealer respondents will each incur an initial (first-year) 48.4 burden hours per respondent,[722] and an annualized burden of 21.8 burden hours per respondent,[723] which remain unchanged from the Commission's preliminary estimates in the Regulation SBSR Proposed Amendments Release.

ii. For Platforms and Registered Clearing Agencies

The Commission is applying the same methodology for calculating the burdens of error reporting by reporting sides to calculating the burdens of error reporting by platforms, under the amendments to Rule 905(a). However, the Commission believes that, on average, a platform will be reporting a greater number of reportable events than, on average, a reporting side. As a result, the Commission believes that a platform will likely be required to report more error corrections than an average reporting side, so the burdens imposed by Rule 905(a) on a platform will likely be greater than the average burden imposed by Rule 905(a) on a reporting side. Thus, for platforms, the Commission estimates that the amendments to Rule 905(a) will impose an initial (first-year) burden of 51.4 hours per platform,[724] and an ongoing annualized burden of 24.8 hours per platform.[725]

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[720] *See* 80 FR at 14681.

[721] *See* 80 FR at 27506.

[722] This figure is calculated as follows: [(((172 burden hours for one-time development of reporting system) × (0.05)) + ((0.68 burden hours annual maintenance of reporting system) × (0.05)) + ((180 burden hours one-time compliance program development) × (0.1)) + ((218 burden hours annual support of compliance program) × (0.1))) × (20 respondents)] = 48.4 burden hours per new broker-dealer respondent. *See supra* nn. 667 and 668 for the discussion of estimates of the burden hours for annual maintenance of the reporting system for these new broker-dealer respondents.

[723] This figure is calculated as follows: [((0.68 burden hours annual maintenance of reporting system) × (0.05)) + ((218 burden hours annual support of compliance program) × (0.1))] = 21.8 burden hours per new broker-dealer respondent. *See supra* nn. 667 and 668 for the discussion of estimates of the burden hours for annual maintenance of the reporting system for these new broker-dealer respondents.

The Commission also believes that this methodology is applicable to the error reporting that will be done by registered clearing agencies as a result of the amendments to Rule 905(a).[726] However, because registered clearing agencies will be responsible for a large number of reportable events, they will likely be required to report more error corrections. As a result, the burdens imposed by Rule 905(a) on registered clearing agencies will be greater. Thus, for registered clearing agencies, the Commission estimates that the amendments to Rule 905(a) will impose an initial (first-year) burden of 153.4 hours per registered clearing agency,[727] and an ongoing annualized burden of 76.8 hours per registered clearing agency.[728]

iii. For Non-Reporting Sides

For non-reporting sides, the Commission estimated in the Regulation SBSR Adopting Release that the annual burden (first-year and each subsequent year) will be 998,640 hours, which corresponds to 208.05 burden hours per non-reporting-side participant.[729] As a result of the amendments adopted herein, there will be more transactions reported to registered SDRs (*i.e.,* clearing transactions and platform-executed transactions that will be submitted to clearing) and thus more transactions that in theory could have errors. If a non-reporting side were to discover any such error, it would incur an obligation under Rule 905(a)(1) to notify the person with the initial duty to report (*i.e.,* the platform or registered clearing agency, as applicable) of the error. The Commission believes, however, that the expansion of Regulation SBSR to include clearing transactions and platform-executed transactions that will be submitted to clearing will not impact non-reporting sides under Rule 905(a)(1). Such transactions will likely be in standardized security-based swap products that occur electronically pursuant to the rules of such entities. Errors, when they occur, will mostly likely be observed and corrected by the platforms or registered clearing agencies themselves. Therefore, the Commission believes that the amendments adopted herein will not increase the burdens per non-reporting side or change the number of non-reporting sides that are required to comply with Rule 905(a)(1). Consequently, the Commission continues to estimate that the annual burden on non-reporting sides pursuant to Rule 905(a)(1) will be 998,640 hours, which corresponds to 208.05 burden hours per non-reporting-side participant.[730]

iv. For Registered SDRs

Rule 905(b) requires a registered SDR to undertake certain actions if it discovers or receives notice of an error in a transaction report. The Commission stated in the Regulation SBSR Adopting Release that it believes that this duty will represent only a minor extension of other duties of registered SDRs for which the Commission is estimating burdens.[731] A registered SDR is required to have the ability to collect and maintain security-based swap transaction reports and update relevant records under the rules adopted in the SDR Adopting Release.[732] Likewise, a registered SDR must have the capacity to disseminate additional, corrected security-based swap transaction reports under Rule 902, the burdens for which were calculated in the Regulation SBSR Adopting Release.[733] Thus, the burdens associated with Rule 905—including systems development, support, and maintenance—are addressed in the Commission's analysis of those other rules.

As discussed above, the Commission estimated in the Regulation SBSR Adopting Release that the initial (first-year) aggregate annualized burden on registered SDRs under Rule 905 will be 21,900 burden hours, which corresponds to 2,190 burden hours for each registered SDR.[734] The Commission further estimated that the ongoing aggregate annualized burden on registered SDRs under Rule 905 will be 14,600 burden hours, which corresponds to 1,460 burden hours for each registered SDR.[735] With respect to Rule 905(a)(2), the Commission stated that the submission of amended transaction reports required under Rule 905(a)(2) likely will not result in a material burden because this will be done electronically though the reporting system that the reporting side must develop and maintain to comply with Rule 901. The overall burdens associated with such a reporting system were addressed in the Commission's analysis of Rule 901.[736]

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[724] *See* Regulation SBSR Proposed Amendments Release, 80 FR at 14794. This figure is calculated as follows: [((172 burden hours for one-time development of reporting system) × (0.05)) + ((60 burden hours annual maintenance of reporting system) × (0.05)) + ((180 burden hours one-time compliance program development) × (0.1)) + ((218 burden hours annual support of compliance program) × (0.1))] = 51.4 burden hours per platform. *See supra* note 679 for the discussion of estimates of the burden hours for annual maintenance of the reporting system for platforms. The Commission notes that the Regulation SBSR Proposed Amendments Release inadvertently used 33 burden hours to represent annual maintenance of the reporting system. The correct figure should have been 60 burden hours for the annual maintenance of the reporting system. As a result, the Commission preliminarily estimated a first-year burden, as a result of proposed amendments to Rule 905(a), of 50 hours instead of the correct first-year burden of 51.4 hours. *See supra* note 684 (calculating the annual reporting burden used to determine the annual maintenance burden of the reporting system).

[725] *See* Regulation SBSR Proposed Amendments Release, 80 FR at 14794. This figure is calculated as follows: [((60 burden hours annual maintenance of reporting system) × (0.05)) + ((218 burden hours annual support of compliance program) × (0.1))] = 24.8 hours per platform. *See supra* note 679 for the discussion of estimates of the burden hours for annual maintenance of the reporting system for platforms. The Commission notes that the Regulation SBSR Proposed Amendments Release inadvertently used 33 burden hours to represent annual maintenance of the reporting system. The correct figure should have been 60 burden hours for the annual maintenance of the reporting system. As a result, the Commission originally estimated an annual ongoing burden, as a result of amendments to Rule 905(a), of 23.5 hours instead of the correct first-year burden of 24.8 hours.

[726] In the Regulation SBSR Proposed Amendments Release, the Commission did not include estimates for the burdens that would be imposed on registered clearing agencies for the reporting of errors under Rule 905(a). Upon further review, the Commission recognizes that registered clearing agencies will be required to report error corrections under Rule 905(a). As a result, the Commission has provided estimates of such burdens herein.

[727] This figure is calculated as follows: [((172 burden hours for one-time development of reporting system) × (0.05)) + ((1100 burden hours annual maintenance of reporting system) × (0.05)) + ((180 burden hours one-time compliance program development) × (0.1)) + ((218 burden hours annual support of compliance program) × (0.1))] = 153.4 burden hours per registered clearing agency. *See also* Regulation SBSR Adopting Release, 80 FR at 14681–83 (describing the manner in which similar burdens were calculated for reporting sides). *See supra* note 679 (discussing estimates of the burden hours for annual maintenance of the reporting system for registered clearing agencies).

[728] This figure is calculated as follows: [((1100 burden hours annual maintenance of reporting system) × (0.05)) + ((218 burden hours annual support of compliance program) × (0.1))] = 76.8 hours per registered clearing agency. *See also* Regulation SBSR Adopting Release, 80 FR at 14681–83 (describing the manner in which similar burdens were calculated for reporting sides). *See supra* note 679 for the discussion of estimates of the burden hours for annual maintenance of the reporting system for platforms.

[729] This figure is based on the following: [(1 error notifications per non-reporting-side participant per day) × (365 days/year) × (Compliance Clerk at 0.5 hours/report) × (4,800 non-reporting-side participants)] = 998,640 burden hours, which corresponds to 208.05 burden hours per non-reporting-side participant. *See* Regulation SBSR Adopting Release, 80 FR at 14681–83.

[730] This figure is based on the following: [(1 error notifications per non-reporting-side participant per day) × (365 days/year) × (Compliance Clerk at 0.5 hours/report) × (4,800 non-reporting-side participants)] = 998,640 burden hours, which corresponds to 208.05 burden hours per non-reporting-side participant. *See* Regulation SBSR Adopting Release, 80 FR at 14681–83.

[731] *See id.* at 14682.

[732] *See* Rules 13n–4(b)(4) and 13n–5 under the Exchange Act, 17 CFR 240.13n–4(b)(4) and 240.13n–5.

[733] *See* 80 FR at 14678.

[734] *See id.* at 14682, n. 1130–32.

The amendments adopted herein do not increase the number of registered SDRs that are respondents to Rule 905(b), but they do increase the number of error reports that will have to be processed by each registered SDR. The Commission notes, however, consistent with its analysis in the Regulation SBSR Adopting Release, that any burdens associated with Rule 905 for registered SDRs are a result of systems development, support, and maintenance and are not dependent on the number of error reports received or processed. Consequently, for registered SDRs, the Commission estimates that the initial (first-year) aggregate annualized burden on registered SDRs under Rule 905, as previously adopted and as amended herein, will be 21,900 burden hours, which corresponds to 2,190 burden hours for each registered SDR.[737] The Commission further estimates that the ongoing aggregate annualized burden on registered SDRs under Rule 905, as previously adopted and as amended herein, will be 14,600 burden hours, which corresponds to 1,460 burden hours for each registered SDR.[738]

v. Aggregate Reporting Burdens Under Rule 905

As discussed above, the Commission estimates that Rule 905(a) will impose an initial (first-year) burden on each reporting side of 50 hours for a total aggregate first-year burden on all reporting sides of 15,000 hours[739] and an ongoing annualized burden on each reporting side of 23.5 hours, for a total aggregate annual burden on all reporting sides of 7,050 hours.[740] The Commission estimates that the 20 new broker-dealer respondents will each incur an initial (first-year) 48.4 burden hours per respondent, for a total aggregate first-year burden on all new broker-dealer respondents of 968 hours,[741] and an ongoing annualized burden of 21.8 burden hours per respondent, for a total aggregate annual burden on all new broker-dealer respondents of 436 hours.[742]

Furthermore, for platforms, the Commission estimates that the amendments to Rule 905(a) will impose an initial (first-year) burden of 51.4 hours per platform for a total aggregate first-year burden on all platforms of 514 hours,[743] and an ongoing annualized burden of 22.1 hours per platform for a total aggregate annual burden on all platforms of 221 hours.[744] The Commission estimates that the amendments to Rule 905(a) will impose an initial (first-year) burden of 153.4 hours per registered clearing agency for a total aggregate first-year burden of 612.6 hours,[745] and an ongoing annualized burden of 76.8 hours per registered clearing agency for a total aggregate annual burden of 307.2 hours.[746]

The Commission estimates that the annual burden on non-reporting sides will remain unchanged at 208.1 burden hours per non-reporting-side participant, for a total aggregate annual burden (first-year and each subsequent year) of 998,640 hours for all non-reporting-side participants.[747]

The Commission estimates that the initial (first-year) aggregate annualized burden on registered SDRs will be 2,190 burden hours for each registered SDR, for a total aggregate first-year burden of 21,900 hours on all registered SDRs.[748] The Commission estimates that the ongoing aggregate annualized burden on registered SDRs will be 1,460 burden hours for each registered SDR, which equals a total aggregate annual burden of 14,600 burden hours for all registered SDRs.[749]

In summary, the Commission estimates that the aggregate first-year burden of Rule 905 for all entities will be 1,037,635 hours.[750] The Commission estimates that the annual burden (after the first year) of Rule 905 for all entities will be 1,021,254 hours.[751]

D. Other Duties of Participants—Rule 906

1. Existing Rule 906

Existing Rule 906(a) sets forth a procedure designed to ensure that a registered SDR obtains relevant UICs for both sides of a security-based swap, not just of the reporting side. Rule 906(a) requires a registered SDR to identify any security-based swap reported to it for which the registered SDR does not have a counterparty ID and (if applicable) broker ID, trading desk ID, and trader ID of each direct counterparty. Rule 906(a) further requires the registered SDR, once a day, to send a report to each participant identifying, for each security-based swap to which that participant is a counterparty, the security-based swap(s) for which the registered SDR lacks counterparty ID and (if applicable) broker ID, trading desk ID, and trader ID. Finally, Rule 906(a) requires a participant that receives such a report to provide the missing ID information to the registered SDR within 24 hours.

Existing Rule 906(b) requires each participant of a registered SDR to provide the registered SDR with information sufficient to identify the participant's ultimate parent(s) and any affiliate(s) of the participant that also are participants of the registered SDR.

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[735] *See id.*, nn. 1131, 1133.

[736] *See id.* at 14675–77.

[737] This figure is based on the following: [(730 burden hours to develop protocols) + (1,460 burden hours annual support)) × (10 registered SDRs)] = 21,900 burden hours, which corresponds to 2,190 burden hours per registered SDR. *See id.* at 14681–83.

[738] This figure is based on the following: [(1,460 burden hours annual support) × (10 registered SDRs)] = 14,600 burden hours, which corresponds to 1,460 burden hours per registered SDR. *See* SBSR Adopting Release, 80 FR at 14681–83.

[739] This figure is calculated as follows: (50.0 burden hours per reporting side × 300 reporting sides) = 15,000 burden hours.

[740] This figure is calculated as follows: (23.5 burden hours per reporting side × 300 reporting sides) = 7,050 burden hours.

[741] This figure is calculated as follows: (48.4 burden hours per new broker-dealer respondent × 20 new respondents) = 968 burden hours.

[742] This figure is calculated as follows: (21.8 burden hours per new broker-dealer respondent × 20 new respondents) = 436 burden hours.

[743] This figure is calculated as follows: (51.4 burden hours per platform × 10 platforms) = 514 burden hours.

[744] This figure is calculated as follows: (22.1 burden hours per platform × 10 platforms) = 221 burden hours.

[745] This figure is calculated as follows: (153.4 burden hours per registered clearing agency × 4 registered clearing agencies) = 612.6 burden hours.

[746] This figure is calculated as follows: (76.8 burden hours per registered clearing agency × 4 registered clearing agencies) = 307.2 burden hours.

[747] This figure is calculated as follows: (208.05 burden hours per non-reporting-side participant × 4,800 non-reporting-side participants) = 998,640 burden hours.

[748] This figure is calculated as follows: (2,190 burden hours per registered SDR × 10 registered SDRs) = 21,900 burden hours.

[749] This figure is calculated as follows: (2,190 burden hours per registered SDR × 10 registered SDRs) = 21,900 burden hours.

[750] This figure is calculated as follows: (15,000 burden hours for reporting sides) + (968 burden hours for new broker-dealer respondents) + (514 burden hours for platforms) + (612.6 burden hours for registered clearing agencies) + (998,640 burden hours for non-reporting-side participants) + (21,900 burden hours for registered SDRs) = 1,037,634.6 burden hours during the first year.

[751] This figure is calculated as follows: (7,050 burden hours for reporting sides) + (436 burden hours for new broker-dealer respondents) + (221 burden hours for platforms) + (307.2 burden hours for registered clearing agencies) + (998,640 burden hours for non-reporting-side participants) + (14,600 burden hours for registered SDRs) = 1,021,254.2 burden hours during each year following the first year.

Existing Rule 906(c) requires each participant that is a registered security-based swap dealer or registered major security-based swap participant to establish, maintain, and enforce written policies and procedures that are reasonably designed to ensure compliance with any security-based swap transaction reporting obligations in a manner consistent with Regulation SBSR. In addition, Rule 906(c) requires each such participant to review and update its policies and procedures at least annually.

For Registered SDRs. Rule 906(a) requires a registered SDR, once a day, to send a report to each of its participants identifying, for each security-based swap to which that participant is a counterparty, any security-based swap(s) for which the registered SDR lacks counterparty ID and (if applicable) broker ID, trading desk ID, and trader ID. In the Regulation SBSR Adopting Release, the Commission estimated that there will be a one-time, initial burden of 112 burden hours for a registered SDR to create a report template and develop the necessary systems and processes to produce a daily report required by Rule 906(a).[752] The Commission estimated that there will be an ongoing annualized burden of 308 burden hours for a registered SDR to generate and issue the daily reports, and to enter into its systems the UIC information supplied by participants in response to the daily reports.[753]

Accordingly, in the Regulation SBSR Adopting Release, the Commission estimated that the initial aggregate annualized burden for registered SDRs under Rule 906(a) will be 4,200 burden hours for all SDR respondents, which corresponds to 420 burden hours per registered SDR.[754] The Commission estimated that the ongoing aggregate annualized burden for registered SDRs under Rule 906(a) will be 3,080 burden hours, which corresponds to 308 burden hours per registered SDR.[755]

For Participants. Existing Rule 906(a) requires any participant of a registered SDR that receives a report from that registered SDR to provide the missing UICs to the registered SDR within 24 hours. All SDR participants will likely be the non-reporting side for at least some transactions to which they are counterparties; therefore, all participants will be impacted by Rule 906(a). In the Regulation SBSR Adopting Release, the Commission estimated that the initial and ongoing annualized burden under Rule 906(a) for all participants will be 199,728 burden hours, which corresponds to 41.6 burden hours per participant.[756]

Existing Rule 906(b) requires every participant of a registered SDR to provide that SDR an initial ultimate parent/affiliate report and updates as needed. In the Regulation SBSR Adopting Release, the Commission estimated that there will be 4,800 participants, that each participant will connect to two registered SDRs on average, and that each participant will submit two Rule 906(b) reports each year.[757] Accordingly, the Commission estimated that the initial and ongoing aggregate annualized burden associated with Rule 906(b) will be 9,600 burden hours, which corresponds to 2 burden hours per participant.[758]

Existing Rule 906(c) requires each participant that is a registered security-based swap dealer or registered major security-based swap participant to establish, maintain, and enforce written policies and procedures that are reasonably designed to ensure compliance with applicable security-based swap reporting obligations, and to review and update such policies and procedures at least annually. In the Regulation SBSR Adopting Release, the Commission estimated that the one-time, initial burden for each covered participant[759] to create these written policies and procedures will be approximately 216 burden hours.[760] The Commission also estimated the burden of maintaining such policies and procedures, including a full review at least annually, will be approximately 120 burden hours for each covered participant.[761] Accordingly, the Commission estimated the initial aggregate annualized burden associated with Rule 906(c) to be 18,480 burden hours, which corresponds to 336 burden hours per covered participant.[762] The Commission estimated the ongoing aggregate annualized burden associated with Rule 906(c) to be 6,600 burden hours, which corresponds to 120 burden hours per covered participant.[763]

In sum, the Commission in the Regulation SBSR Adopting Release estimated that the total initial aggregate annualized burden associated with Rule 906 will be 230,370 burden hours, and that the total ongoing aggregate annualized burden will be 217,370 burden hours for all participants.[764]

2. Amendments to Rule 906

a. Rule 906(a)

In this release, the Commission is making only a minor amendment to Rule 906(a)[765] which does not affect the estimated number of respondents or the estimated burdens for existing respondents to the rule.

However, because of the amendments to Rule 901(a) adopted herein, the scope of transactions covered by Regulation SBSR is increasing. As a result, a registered SDR will have to review a larger number of transactions to assess whether there is missing UIC information. The Commission believes that the process whereby a registered SDR reviews transactions and generates the associated reports will be automated, and that the costs of performing this automated review will be approximately the same even if the review covers a larger set of transactions. Furthermore, although Rule 906(a) notices sent by a registered SDR could in some cases be longer because they cover more transactions, the amendments to Rule 901(a) will not increase the number of participants (4,800) to which the registered SDR will likely have to send such notices. Therefore, the Commission does not believe that the larger number of transactions will result in any burdens on registered SDRs under Rule 906(a) that were not already accounted for in the Regulation SBSR Adopting Release.[766] Thus, the Commission

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[752] *See* 80 FR at 14683–85.

[753] *See id.*

[754] *See id.*

[755] *See id.*

[756] This figure is based on the Commission's estimates of 4,800 participants and approximately 1.14 transactions per day per participant. *See id.*

[757] *See id.* The Commission estimated that, during the first year, each participant will submit an initial report and one update report and, in subsequent years, will submit two update reports.

[758] *See id.* This estimated aggregate burden represents an upper estimate for all participants; the actual burden could be reduced to the extent that the registered SDR permits one member of the group to report the ultimate parent(s) and affiliates on behalf of each participant member of the group. *See supra* note 608.

[759] Only some participants of registered SDRs are subject to the requirements of Rule 906(c). As used in this release, any participant that is "covered" by Rule 906(c) is deemed a "covered participant."

[760] This figure is based on the estimated number of hours to develop a set of written policies and procedures, program systems, implement internal controls and oversight, train relevant employees, and perform necessary testing. *See* 80 FR at 14684.

[761] This figure includes an estimate of hours related to reviewing existing policies and procedures, making necessary updates, conducting ongoing training, maintaining internal controls systems, and performing necessary testing. *See id.*

[762] *See id.*

[763] *See id.*

[764] *See id.*

[765] *See supra* note 312.

[766] The Commission estimated that a registered SDR will incur an initial, one-time burden of 112 hours to create a report template and develop the necessary systems and processes to produce a daily report required by Rule 906(a). The Commission

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believes that its original burden estimates for registered SDRs to comply with Rule 906(a) remain appropriate.

With respect to the 4,800 participants that will likely be required to provide missing UIC information to a registered SDR for at least some transactions, the Commission is revising its original estimate of the burdens imposed by Rule 906(a) because participants will have to provide missing UIC information for a larger number of transactions. Although a registered SDR's process for generating a Rule 906(a) notice is likely to be automated, at least some participants might rely on manual procedures to reply. In the Regulation SBSR Adopting Release, the Commission estimated that the initial and ongoing annualized burden under Rule 906(a) for all participants will be 199,728 burden hours, which corresponds to 41.6 burden hours per participant.[767]

The Commission continues to believe that there will be approximately one million additional reportable events under Regulation SBSR.[768] Of these one million reportable events, the Commission estimates that approximately 120,000 platform-executed alphas reflected in estimates in the Regulation SBSR Adopting Release could have missing UIC information. Both sides of a platform-executed alpha might have to report missing UIC information since neither side is the reporting side and thus both sides are non-reporting sides. Therefore, the Commission believes that each participant, on average, will now be required to provide missing UIC information for 1.27 transactions each day.[769] As a result, the Commission believes that the burden placed on each participant by Rule 906(a) will be 46.4 hours annually,[770] for a total burden of 222,504 hours for all participants.

b. Rule 906(b)—Amendments

Existing Rule 906(b) requires each participant of a registered SDR to provide the registered SDR information sufficient to identify its ultimate parent(s) and any affiliate(s) of the participant that also are participants of the registered SDR, using ultimate parent IDs and participant IDs. In this release, the Commission is adopting amendments to Rule 906(b) to *exclude* from this reporting requirement participants that are platforms, registered clearing agencies, externally managed investment vehicles, and registered broker-dealers (including SB SEFs) that become participants of a registered SDR solely as a result of making a report to satisfy an obligation under Rule 901(a)(2)(ii)(E)(*4*). Therefore, this amendment does not create any new respondents that have burdens under the rule or increase burdens for any existing respondents.

Platforms and registered clearing agencies were not covered respondents to Rule 906(b) when the Commission estimated the burdens of Rule 906(b), as adopted in the Regulation SBSR Adopting Release. Therefore, the amendment to Rule 906(b) adopted today that specifically excludes them does not affect the Commission's estimate in the Regulation SBSR Adopting Release of the burdens associated with Rule 906(b).

However, externally managed investment vehicles *were* considered respondents of Rule 906(b), as adopted in the Regulation SBSR Adopting Release, and the estimated burdens on all participant respondents in that adopting release included burdens imposed on externally managed investment vehicles.[771] Therefore, the amendment to Rule 906(b) adopted herein that excludes externally managed investment vehicles has the effect of reducing the number of respondents and the associated burdens of Rule 906(b) that the Commission estimated in the Regulation SBSR Adopting Release. Based on an analysis of TIW transaction data, the Commission believes that, of the 4,800 estimated participants, approximately 1,920 are externally managed investment vehicles.[772] Therefore, the Commission now estimates that there are only 2,880 participant respondents to Rule 906(b), as amended herein. In the Regulation SBSR Adopting Release, the Commission further estimated that each respondent to Rule 906(b) will submit two reports per year and that each report will result in one burden hour.[773] The Commission continues to believe that each respondent will incur two burden hours per year in connection with Rule 906(b), but is reducing its estimate of total burden hours for all participants from 9,600 (estimated in the Regulation SBSR Adopting Release) to 5,760 (2,880 respondents × 2 hours/respondent = 5,760 hours).

c. Rule 906(c)—Amendments

i. Summary of Collection of Information

Persons that are subject to Rule 906(c) must establish, maintain, and enforce written policies and procedures that are reasonably designed to ensure compliance with applicable security-based swap transaction reporting obligations. Respondents also must review and update their policies and procedures at least annually.

ii. Respondents

The amendments to Rule 906(c) adopted today will extend the requirements of existing Rule 906(c) to registered clearing agencies, platforms, and registered broker-dealers that incur duties to report security-based swaps pursuant to Rule 901(a)(2)(ii)(E)(*4*). The Commission estimates that there will be 4 registered clearing agencies, 10 platforms, and 20 registered broker-dealers that will become subject to Rule 906(c).

iii. Total Initial and Annual Reporting and Recordkeeping Burdens

For Registered Clearing Agencies and Platforms. In the Regulation SBSR Proposed Amendments Release, the Commission preliminarily estimated that the one-time, initial burden for each registered clearing agency or platform to adopt written policies and procedures as required under the amendment to Rule 906(c) would be similar to the Rule 906(c) burdens for other covered

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also estimated that a registered SDR will incur an ongoing annualized burden of 308 hours to generate and issue the daily reports, and to enter into its systems the ID information supplied by participants in response to the daily reports. *See* Regulation SBSR Adopting Release, 80 FR at 14684.

[767] This figure is based on the Commission's estimates of (1) 4,800 participants; and (2) approximately 1.14 transactions per day per participant. *See id.*

[768] *See* Regulation SBSR Adopting Release, 80 FR at 14675–76.

[769] The Commission originally estimated that participants could have to provide missing UIC information for up to two million security-based swap transactions annually. This results in each participant, on average, having to provide missing information for 1.14 transactions each day. As a result, the Commission originally estimated the total burden to be 199,728 hours, or 41.6 hours annually for each participant. *See* 80 FR at 14684. The Commission now believes that these same participants will be responsible for providing missing UIC information for a greater number of security-based swap transactions. The Commission estimates: [(((2,000,000 original estimate of annual security-based swap transactions for which mission UIC information would need to be provided to the SDR) + ((120,000 additional security-based swap transactions for which UIC information is required) × (2 since both sides could be required to provide missing UIC information)))/4,800 participants)/(365 days/year)] = 1.27 average security-based swap transactions per day for which each participant will need to provide missing UIC information.

[770] The Commission estimates that the total burden for all participants will be 222,504 calculated as follows: (1.27 missing information reports per day) × (365 days per year) × (Compliance Clerk at 0.1 hours/report) × (4,800 participants) = 222,504 hours/year or 46.4 hours for each participant.

[771] *See* 80 FR at 14684.

[772] Roughly 40% of TIW accounts on average have been identified by staff as private funds or registered investment companies, 4,800 × 0.4 = 1,920.

[773] *See id.*

participants.[774] In the Regulation SBSR Adopting Release, the Commission estimated that Rule 906(c) will impose a burden of approximately 216 hours on each registered security-based swap dealer or registered major security-based swap participant (together, "covered participants").[775] In addition, the Commission estimated that the burden of maintaining such policies and procedures, including a full review at least annually, will be approximately 120 burden hours for each covered participant.[776] The Commission continues to believe that, by amending Rule 906(c) to apply the policies and procedures requirement to registered clearing agencies and platforms, these entities will face burdens similar to those of the existing covered participants. Accordingly, the Commission estimates that the initial aggregate annualized burden associated with the amendments to Rule 906(c) will be 4,704 burden hours, which corresponds to 336 burden hours per registered clearing agency or platform.[777] The Commission estimates that the ongoing aggregate annualized burden associated with the amendments to Rule 906(c) will be 1,680 burden hours, which corresponds to 120 burden hours per registered clearing agency or platform.[778]

For Registered Broker-Dealers. The amendments to Rule 906(c) will require each registered broker-dealer that becomes a participant solely as a result of incurring a reporting duty under Rule 901(a)(2)(ii)(E)(*4*) (a "respondent broker-dealer") to establish, maintain, and enforce written policies and procedures that are reasonably designed to ensure compliance with applicable security-based swap transaction reporting obligations. The amendments to Rule 906(c) also will require each respondent broker-dealer to review and update such policies and procedures at least annually.

In the U.S. Activity Proposal, the Commission preliminarily estimated that the one-time, initial burden for each respondent broker-dealer to adopt written policies and procedures as required under the amendment to Rule 906(c) would be similar to the Rule 906(c) burdens for existing covered participants.[779] In the Regulation SBSR Adopting Release, the Commission estimated that Rule 906(c) will impose a burden of approximately 216 hours on each covered participant.[780] In addition, the Commission estimated that the burden of maintaining such policies and procedures, including a full review at least annually, will be approximately 120 burden hours for each covered participant.[781] The Commission continues to believe that, by amending Rule 906(c) to impose the policies and procedures requirement on respondent broker-dealers, these entities will face burdens similar to those of other covered participants. Accordingly, the Commission estimates that the initial aggregate annualized burdens on respondent broker-dealers associated with the amendment to Rule 906(c) will be 6,720 burden hours, which corresponds to 336 burden hours per respondent broker-dealer.[782] The Commission estimates that the ongoing aggregate annualized burdens on all respondent broker-dealers associated with the amendments to Rule 906(c) will be 2,400 burden hours, which corresponds to 120 burden hours per respondent broker-dealer.[783]

3. Rule 906—Aggregate Total PRA Burdens and Costs

Based on the foregoing, the Commission estimates the following aggregate total PRA burdens and costs, by category of entity, resulting from Rule 906. These figures add the burdens and costs estimated in the Regulation SBSR Adopting Release for the existing covered participants with the burdens and costs estimated for the additional covered participants resulting from the amendments to Rule 906(c) adopted herein.

a. For Platforms and Registered Clearing Agencies

The Commission estimates that the one-time, initial burden for each registered clearing agency or platform to adopt written policies and procedures as required under the amendments to Rule 906(c) will be similar to the Rule 906(c) burdens discussed in the Regulation SBSR Adopting Release for covered participants, and will be approximately 216 burden hours per registered clearing agency or platform.[784] This figure is based on the estimated number of hours to develop a set of written policies and procedures, program systems, implement internal controls and oversight, train relevant employees, and perform necessary testing. In addition, the Commission estimates the burden of maintaining such policies and procedures, including a full review at least annually, as required by Rule 906(c), will be approximately 120 burden hours for each registered clearing agency or platform.[785] This figure includes an estimate of hours related to reviewing existing policies and procedures, making necessary updates, conducting ongoing training, maintaining internal controls systems, and performing necessary testing. Accordingly, the Commission estimates that the initial, or first year, aggregate annualized burden associated with the amendments to Rule 906(c) will be 4,704 burden hours, which corresponds to 336 burden hours per registered clearing agency or platform.[786] The Commission estimates that the ongoing aggregate annualized burden associated with the amendments to Rule 906(c) will be 1,680 burden hours, which corresponds to 120 burden hours per registered clearing agency or platform.[787]

b. For Registered SDRs

As a result of changes in other rules, registered SDRs will have to identify missing UIC information from a larger number of transactions and send more requests to non-reporting sides seeking such missing UIC information.

In the Regulation SBSR Adopting Release, the Commission estimated that there will be a one-time, initial burden of 112 burden hours for each registered SDR to create a report template and develop the necessary systems and processes to produce a daily report required by Rule 906(a), or 1,120 burden hours for all SDRs.[788] The Commission believes that this estimate continues to be valid, as an SDR's initial investment in the infrastructure necessary to carry out its duties under Rule 906(a) should be unaffected by the precise number of transactions covered by Regulation SBSR.

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[774] *See* 80 FR at 14797.

[775] *See id.* This figure is based on the following: [(Sr. Programmer at 40 hours) + (Compliance Manager at 40 hours) + (Compliance Attorney at 40 hours) + (Compliance Clerk at 40 hours) + (Sr. Systems Analyst at 32 hours) + (Director of Compliance at 24 hours)] = 216 burden hours per registered clearing agency or platform. This figure is based on the estimated number of hours to develop a set of written policies and procedures, program systems, implement internal controls and oversight, train relevant employees, and perform necessary testing.

[776] *See id.* This figure is based on the following: [(Sr. Programmer at 8 hours) + (Compliance Manager at 24 hours) + (Compliance Attorney at 24 hours) + (Compliance Clerk at 24 hours) + (Sr. Systems Analyst at 16 hours) + (Director of Compliance at 24 hours)] = 120 burden hours per registered clearing agency or platform. This figure includes an estimate of hours related to reviewing existing policies and procedures, making necessary updates, conducting ongoing training, maintaining internal controls systems, and performing necessary testing.

[777] This figure is based on the following: [(216 + 120 burden hours) × (14 registered clearing agencies and platforms)] = 4,704 burden hours.

[778] This figure is based on the following: [(120 burden hours) × (14 registered clearing agencies and platforms)] = 1,680 burden hours.

[779] *See* U.S. Activity Proposal, 80 FR at 27506.

[780] *See supra* note 775.

[781] *See supra* note 776.

[782] This figure is based on the following: (216 + 120 burden hours) × (20 respondent broker-dealers = 6,720 burden hours.

[783] This figure is based on the following: (120 burden hours) × (20 respondent broker-dealers) = 2,400 burden hours.

[784] *See supra* note 775.

[785] *See supra* note 776.

[786] *See supra* note 777.

[787] *See supra* note 778.

In the Regulation SBSR Adopting Release, the Commission estimated that there will be an ongoing annualized burden of 308 burden hours for each registered SDR to generate and issue the daily reports, and to enter into its systems the UIC information supplied by participants in response to the daily reports, or 3,308 burden hours for all SDRs.[789] Although the scope of security-based swap transactions covered by Regulation SBSR has increased, the Commission continues to believe that there will be an ongoing annualized burden of 308 burden hours for a registered SDR to generate and issue the daily reports, and to enter into its systems the UIC information supplied by participants in response to the daily reports.

c. For Participants

The Commission estimates that, as a result of the amendments adopted herein, the initial and ongoing annualized burden under Rule 906(a) for all participants will be 222,504 burden hours, which corresponds to 46.4 burden hours per participant.[790] The Commission notes that each participant will, on average, have to provide missing UIC information for more security-based swap transactions than it would have prior to the amendments adopted in this release. The revised estimates account for these additional transactions.

In the Regulation SBSR Adopting Release, the Commission estimated that the initial and ongoing aggregate annualized burden associated with Rule 906(b) will be 9,600 burden hours, which corresponds to 2 burden hours per participant.[791] The amendment to Rule 906(b) does not create any new respondents or impose any new burdens on existing respondents, as the amendment excludes platforms, registered clearing agencies, registered broker-dealers, and externally managed investment vehicles from having to report ultimate parent and affiliate information to registered SDRs of which they are participants. Therefore, the Commission's estimate of the burdens imposed by Rule 906(b) on individual participants remains unchanged. However, because of the exclusions discussed above, only 2,880 participants will be subject to the requirement of Rule 906(b). As a result, the aggregate annualized burden associated with Rule 906(b) will fall from 9,600 hours (estimated in the Regulation SBSR Adopting Release) to 5,760 hours.

d. For New Broker-Dealer Respondents

In this release, the Commission is adopting an amendment to Rule 906(c) that extends the requirement to establish policies and procedures for carrying out reporting duties under Regulation SBSR to platforms, registered clearing agencies, and registered broker-dealers that incur a duty to report security-based swaps under new Rule 901(a)(2)(ii)(E)(*4*). The Commission estimates 20 registered broker-dealers will become subject to Rule 906(c). The Commission discussed the burdens placed upon platforms and registered clearing agencies as a result of the amendments to Rule 906(c) in Section XI(D)(3)(a), *supra*. The Commission believes that the per-respondent costs of establishing and updating the required policies will be the same for new broker-dealer respondents identified in this release as well as the respondents identified in the Regulation SBSR Adopting Release, as discussed in Section XI(D)(1), *supra*. Therefore, the Commission estimates that the new broker-dealer respondents will incur a one-time, initial burden of 216 burden hours per new broker-dealer respondent, or 6,480 hours for all new broker-dealer respondents, and an ongoing annual burden of 120 hours per new broker-dealer respondent, or 2,400 hours for all new broker-dealer respondents.

e. Aggregate Rule 906 Burdens

In sum, Rule 906(a) will place a total first-year burden on registered SDRs of 1,120 hours.[792] Rule 906(a) will place a total annual burden on registered SDRs and covered participants of 269,384 hours.[793] Rule 906(b) will place a total annual burden on covered participants of 5,760 hours.[794] Rule 906(c) will place a total first-year burden on covered participants of 19,224 hours.[795] Rule 906(c) will place a total annual burden on covered participants of 10,680 hours.[796] These figures combine the burdens associated with Rule 906 estimated in the Regulation SBSR Adopting Release with the revisions to these burdens associated with the amendments to Rule 906 adopted herein.

E. Policies and Procedures of Registered SDRs—Rule 907

1. Existing Rule 907

Existing Rule 907(a) requires a registered SDR to establish and maintain written policies and procedures with respect to the receipt, reporting, and public dissemination of security-based swap transaction information. Existing Rule 907(c) requires a registered SDR to make its policies and procedures available on its Web site. Existing Rule 907(d) requires a registered SDR to review, and update as necessary, the policies and procedures that it is required to have by Regulation SBSR at least annually. Existing Rule 907(e) requires a registered SDR to provide to the Commission, upon request, information or reports related to the timeliness, accuracy, and completeness of data reported to it pursuant to Regulation SBSR and the registered SDR's policies and procedures established thereunder.

2. Rule 907—Amendments

In this release, the Commission is making only one amendment to Rule 907: The Commission is revising Rule 907(a)(6) to carve out platforms, registered clearing agencies, externally managed investment vehicles, and registered broker-dealers (including SB SEFs) that become a participant of a registered SDR solely as a result of making a report to satisfy an obligation under Rule 901(a)(2)(ii)(E)(*4*) from the requirement in Rule 907(a)(6) that a registered SDR have policies and procedures for obtaining ultimate parent and affiliate information from its participants, as contemplated by an amendment to Rule 906(b) adopted herein. The amendment to Rule 907(a)(6) has the effect of preventing existing respondent SDRs from incurring additional burdens because they will not have to obtain ultimate parent and affiliate information from additional types of participants.

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[788] *See* 80 FR at 14683–85.

[789] *See id.*

[790] *See supra* note 770 and accompanying text.

[791] *See* Regulation SBSR Adopting Release, 80 FR at 14683–85. This figure is based on the following: [(Compliance Clerk at 0.5 hours per report) × (2 reports/year/SDR connection) × (2 SDR connections/participant) × (4,800 participants)] = 9,600 burden hours, which corresponds to 2 burden hours per covered participant.

[792] The Commission calculated this estimate as follows: (112 hours (first year burden on SDRs as a result of Rule 906(a)) × 10 SDRs) = 1,120 hours.

[793] The Commission calculated this estimate as follows: ((308 hours (annual burden on SDRs as a result of Rule 906(a)) × 10 SDRs)) + ((55.5 hours (annual burden on participants as a result of Rule 906(a)) × 4,800 participants) = 269,384 hours.

[794] The Commission calculated this estimate as follows: (2 hours (annual burden on participants as a result of Rule 906(b)) × 2,880 revised number of participants impacted by Rule 906(b)) = 5,760 hours.

[795] The Commission calculated this estimate as follows: (216 hours (first-year burden on each respondent) × 89 respondents (*i.e.*, 55 registered security-based swap dealers + registered major security-based swap participants + 20 new broker-dealer respondents + 14 platforms and registered clearing agencies) = 19,224 hours.

[796] The Commission calculated this estimate as follows: (120 hours (annual burden per covered participants) × 89 covered participants) = 10,680 hours.

However, amendments to other rules in Regulation SBSR will have the effect of requiring a registered SDR to expand its policies and procedures to cover additional types of reporting persons and additional types of reporting scenarios. For example, platforms and registered broker-dealers may now incur duties to report certain security-based swaps and are required to become participants of registered SDRs to which they report. In addition, a registered clearing agency also incurs the duty to report to the alpha SDR whether the clearing agency has accepted an alpha for clearing. Registered SDRs that record alpha transactions will have to expand their policies and procedures to be able to link the report of the original alpha transaction (which would be reported either by a reporting side or, if the alpha was platform-executed and will be submitted to clearing, by the platform) to the report of the clearing disposition, which would be submitted by the registered clearing agency.

3. Rule 907—Aggregate Total PRA Burdens and Costs

In the Regulation SBSR Adopting Release, the Commission estimated that the one-time, initial burden for a registered SDR to adopt written policies and procedures as required under existing Rule 907 will be approximately 15,000 hours. In addition, the Commission estimated the annual burden of maintaining such policies and procedures, including a full review at least annually, making available its policies and procedures on the registered SDR's Web site, and information or reports on non-compliance (as required under Rule 907(e)) will be approximately 30,000 hours for each registered SDR. The Commission estimated that the total initial annualized burden associated with Rule 907 will be approximately 45,000 hours per registered SDR, which corresponds to an initial annualized aggregate burden of approximately 450,000 hours.[797] The Commission further estimated that the ongoing annualized burden associated with Rule 907 will be approximately 30,000 hours per registered SDR,[798] which corresponds to an ongoing annualized aggregate burden of approximately 300,000 hours.[799]

As a result of amendments made to various provisions of Regulation SBSR in this release, registered SDRs will need to broaden the scope of the written policies and procedures that Rule 907 requires them to have.[800] The Commission believes that a registered SDR's expansion of its policies and procedures in response to the amendments to Regulation SBSR adopted in this release represents an "add-on" to the burdens already calculated with respect to the SDR policies and procedures under existing Rule 907. The Commission estimates the incremental burden to be an additional 10% of the one-time and annual burdens estimated to result from existing Rule 907.

Accordingly, the Commission believes that the one-time, initial burden for a registered SDR to adopt written policies and procedures as required under Rule 907 will be approximately 16,500 hours.[801] In addition, the Commission estimates the annual burden of maintaining such policies and procedures, including a full review at least annually, making available its policies and procedures on the registered SDR's Web site, and information or reports on non-compliance, as required under Rule 907(e), will be approximately 33,000 hours for each registered SDR.[802] The Commission therefore estimates that the initial annualized burden associated with Rule 907 will be approximately 45,000 hours per registered SDR, which corresponds to an initial annualized aggregate burden of approximately 495,000 hours.[803] The Commission further estimates that the ongoing annualized burden associated with Rule 907 will be approximately 33,000 hours per registered SDR, which corresponds to an ongoing annualized aggregate burden of approximately 330,000 hours.[804]

F. Cross-Border Matters—Rule 908

1. Existing Rule 908

Rule 908(a) defines when certain cross-border security-based swap transactions are subject to regulatory reporting and/or public dissemination. Rule 908(a), as adopted in the Regulation SBSR Adopting Release, covered security-based swaps consisting of only certain counterparty pairs. Existing Rule 908(a)(1)(i) provides that a security-based swap shall be subject to regulatory reporting and public dissemination if "[t]here is a direct or indirect counterparty that is a U.S. person on either or both sides of the transaction," and existing Rule 908(a)(1)(ii) provides that a security-based swap shall be subject to regulatory reporting and public dissemination if "[t]he security-based swap is submitted to a clearing agency having its principal place of business in the United States." Existing Rule 908(a)(2) provides that a security-based swap not included within Rule 908(a)(1) would be subject to regulatory reporting but not public dissemination "if there is a direct or indirect counterparty on either or both sides of the transaction that is a registered security-based swap dealer or a registered major security-based swap participant." Rule 908(a), as adopted in the Regulation SBSR Adopting Release, did not otherwise address when an uncleared security-based swap involving only unregistered non-U.S. persons would be subject to regulatory reporting and/or public dissemination.

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[797] This figure is based on the following: [((15,000 burden hours per registered SDR) + (30,000 burden hours per registered SDR)) × (10 registered SDRs)] = 450,000 initial annualized aggregate burden hours during the first year.

[798] *See* Regulation SBSR Adopting Release, 80 FR at 14685. This figure is based on the following: [(Sr. Programmer at 3,333 hours) + (Compliance Manager at 6,667 hours) + (Compliance Attorney at 10,000 hours) + (Compliance Clerk at 5,000 hours) + (Sr. System Analyst at 3,333 hours) + (Director of Compliance at 1,667 hours)] = 30,000 burden hours per registered SDR.

[799] *See* Regulation SBSR Adopting Release, 80 FR at 14685–86. This figure is based on the following: [(30,000 burden hours per registered SDR) × (10 registered SDRs)] = 300,000 ongoing, annualized aggregate burden hours.

[800] For example, new Rule 901(e)(1)(ii) requires a registered clearing agency to report to the alpha SDR whether or not it has accepted the alpha for clearing. The alpha SDR must revise its policies and procedures to allow for the information from the registered clearing agency to be connected to the initial report of the alpha. *See supra* Section III(G). In addition, new Rule 902(c)(8) requires a registered SDR to avoid public dissemination of a security-based swap that has been rejected from clearing or rejected by a prime broker if the original transaction report has not yet been publicly disseminated. *See supra* Section III(J). A registered SDR must adjust its policies and procedures for public dissemination to comply with new Rule 902(c)(8).

[801] This figure is calculated as follows: [15,000 one-time written policies and procedures development × (1.1)] = 16,500.

[802] This figure is calculated as follows: [(30,000 one-time written policies and procedures development × (1.1)] = 33,000.

[803] This figure is based on the following: [((16,500 burden hours per registered SDR) + (33,000 burden hours per registered SDR)) × (10 registered SDRs)] = 495,000 initial annualized aggregate burden hours during the first year.

[804] This figure is based on the following: [(33,000 burden hours per registered SDR) × (10 registered SDRs)] = 330,000 ongoing, annualized aggregate burden hours.

Rule 908(b) defines when a person might incur obligations under Regulation SBSR. Existing Rule 908(b) provides that, notwithstanding any other provision of Regulation SBSR, a person shall not incur any obligation under Regulation SBSR unless it is a U.S. person, a registered security-based swap dealer, or a registered major security-based swap participant.

The Commission stated in the Regulation SBSR Adopting Release that Rules 908(a) and 908(b) do not impose any collection of information requirements and that, to the extent that a security-based swap transaction or a person is subject to Rule 908(a) or (b), respectively, the collection of information burdens are calculated as part of the underlying rule (*e.g.,* Rule 901, which imposes the basic duty to report security-based swap transaction information).[805]

Existing Rule 908(c) sets forth the requirements for a substituted compliance request relating to regulatory reporting and public dissemination of security-based swaps in a particular foreign jurisdiction, and is the only part of Rule 908 to impose paperwork burdens. Rule 908(c) is not being amended by this release. In the Regulation SBSR Adopting Release, the Commission estimated that it will receive approximately ten substituted compliance requests in the first year and two requests each subsequent year.[806] The total paperwork burden associated with submitting a request for a substituted compliance determination with respect to regulatory reporting and public dissemination will be approximately 1,120 hours, plus $1,120,000 for 14 estimated requests.[807] In the Regulation SBSR Adopting Release, the Commission estimated that it would receive ten requests in the first year resulting in an aggregated burden for the first year of 800 hours, plus $800,000 for the services of outside professionals.[808] The Commission further estimates that it would receive two requests in each subsequent year resulting in an aggregate annual burden, after the first year, of up to 160 hours of company time and $160,000 for the services of outside professionals.[809]

2. Rule 908—Amendments

The Commission today is adopting amendments to Rule 908(a) to subject additional types of security-based swap transactions to regulatory reporting and public dissemination under Regulation SBSR, and amendments to Rule 908(b) to clarify that additional types of persons may incur duties under Regulation SBSR. However, these amendments do not themselves impose any paperwork burdens. Additional paperwork burdens caused by increasing the number of respondents or by increasing the burdens imposed on respondents are considered under the rule that imposes the substantive duties. The Commission is not amending Rule 908(c) herein.

3. Rule 908—Aggregate Total Burdens and Costs

Because the only part of Rule 908 that imposes any paperwork burdens is paragraph (c), the Commission's estimate from the Regulation SBSR Adopting Release of the total paperwork burden associated with Rule 908(c) remains approximately 1,120 hours, plus $1,120,000 for 14 substituted compliance requests.[810] The Commission continues to believe that the first-year aggregated burden will be 800 hours, plus $800,000 for the services of outside professionals, and that the aggregate burden for each year following the first year will be up to 160 hours of company time and $160,000 for the services of outside professionals.[811]

G. Additional PRA Discussion

1. Use of Information

The security-based swap transaction information that is required by the amendments to Regulation SBSR adopted herein will be used by registered SDRs, market participants, the Commission, and other relevant authorities. The information reported by respondents pursuant to the amendments to Regulation SBSR adopted herein will be used by registered SDRs to publicly disseminate reports of security-based swap transactions, as well as to offer a resource for the Commission and other relevant authorities to obtain detailed information about the security-based swap market. Market participants also will use the information about these transactions that is publicly disseminated, among other things, to assess the current market for security-based swaps and any underlying and related securities, and to assist in the valuation of their own positions. The Commission and other relevant authorities will use information about security-based swap transactions reported to and held by registered SDRs to monitor and assess systemic risks, as well as to examine for and consider whether to take enforcement action against potentially abusive trading behavior, as appropriate.

The policies and procedures required under the amendments to Regulation SBSR will be used by participants to aid in their compliance with Regulation SBSR, and also used by the Commission as part of its ongoing efforts to monitor and enforce compliance with the federal securities laws, including Regulation SBSR, through, among other things, examinations and inspections.

2. Recordkeeping Requirements

Apart from the duty to report certain transaction information, Regulation SBSR does not impose any recordkeeping requirement on reporting sides.

Security-based swap transaction information received by a registered SDR pursuant to Regulation SBSR is subject to Rule 13n–5(b)(4) under the Exchange Act,[812] which requires an SDR to maintain such information for not less than five years after the applicable security-based swap expires and historical positions for not less than five years. Rule 13n–7(b) under the Exchange Act[813] requires the SDR to keep and preserve at least one copy of all documents, including all documents and policies and procedures required by the Exchange Act and the rules or regulations thereunder, for a period of not less than five years, the first two years in a place that is immediately available to representatives of the Commission for inspection and examination. The Commission does not believe that the amendments to Regulation SBSR adopted herein will have any impact on the PRA burdens of registered SDRs related to recordkeeping as they were already accounted for in the SDR Adopting Release.[814]

The Commission has proposed recordkeeping requirements for registered clearing agencies[815] and SB SEFs.[816] The amendments to Regulation SBSR adopted herein do not impose any recordkeeping requirements on registered clearing agencies or platforms.

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[805] *See* 80 FR at 14686.

[806] *See id.*

[807] *See id.* at 14687.

[808] *See id.*

[809] *See id.*

[810] *See id.*

[811] *See id.*

[812] 17 CFR 240.13n–5(b)(4).

[813] 17 CFR 240.13n–7(b).

[814] *See* 80 FR at 14523–24 (discussing the burdens associated with the recordkeeping requirements of Rules 13n–5(b)(4) and 13n–7(b)).

[815] *See* Securities Exchange Act Release No. 64017 (March 3, 2011), 76 FR 14472 (March 16, 2011) ("Clearing Agency Standards for Operation and Governance Proposing Release").

[816] *See* Securities Exchange Act Release No. 63825 (February 2, 2011), 76 FR 10948 (February 29, 2011) ("SB SEF Proposing Release").

3. Collection of Information Is Mandatory

Each collection of information discussed above is mandatory.

4. Confidentiality of Responses to Collection of Information

An SDR, pursuant to Section 13(n)(5)(F) of the Exchange Act[817] and Rules 13n–4(b)(8) and 13n–9 thereunder,[818] is required to maintain the privacy of the security-based swap transaction information that it receives. For the majority of security-based swap transactions, the information collected pursuant to Rule 901(c) by a registered SDR will be publicly disseminated. Furthermore, to the extent that information previously reported and publicly disseminated is corrected, such information also will be widely available. However, certain security-based swaps are not subject to Rule 902's public dissemination requirement; therefore, information about these transactions will not be publicly available. For all security-based swaps, the information collected pursuant to Rule 901(d) is for regulatory purposes and will not generally be available to the public, although the Commission or Commission staff may make available statistics or aggregated data derived from these transaction reports. To the extent that the Commission receives confidential information pursuant to this collection of information, such information would be kept confidential, subject to the provisions of applicable law.

XII. Economic Analysis

The Dodd-Frank Act amended the Exchange Act, among other things, to require regulatory reporting and public dissemination of security-based swap transactions. Regulation SBSR, which the Commission adopted in February 2015, implements this mandate. At the same time that it adopted Regulation SBSR, the Commission proposed additional rules and guidance to address issues that were not resolved in the Regulation SBSR Adopting Release.[819] Later, in April 2015, the Commission issued the U.S. Activity Proposal, which (among other things) proposed further amendments to Regulation SBSR to address the reporting and public dissemination of additional types of cross-border security-based swaps.[820] In this release, the Commission is adopting, with certain revisions, the amendments to Regulation SBSR contained in the Regulation SBSR Proposed Amendments Release and the U.S. Activity Proposal.

The Commission is sensitive to the economic consequences and effects, including costs and benefits, of its rules. Some of these costs and benefits stem from statutory mandates, while others are affected by the discretion exercised in implementing these mandates. The following economic analysis identifies and considers the benefits and costs that could result from the amendments adopted herein. The Commission also discusses the potential economic effects of certain alternatives to the approach taken by these amendments. To the extent applicable, the views of commenters relevant to the Commission's analysis of the economic effects, costs, and benefits of these amendments are included in the discussion below.

A. Programmatic Costs of Amendments to Regulation SBSR

In this section, the Commission discusses the programmatic costs and benefits associated with the amendments to Regulation SBSR adopted in this release. This discussion includes a summary of and response to comments relating to the Commission's initial analysis of the costs and benefits associated with these amendments.

1. Programmatic Costs of Newly Adopted Requirements

New Rule 901(a)(2)(i) provides that the reporting side for a clearing transaction is the registered clearing agency that is a direct counterparty to the clearing transaction, and allows the registered clearing agency to select the SDR. New Rule 901(a)(3) requires any person that has a duty to report a security-based swap that has been submitted to clearing at a registered clearing agency to promptly provide that registered clearing agency with the transaction ID of the submitted security-based swap and the identity of the registered SDR to which the transaction will be reported or has been reported. These amendments to Rule 901 will impose initial and ongoing costs on platforms, registered clearing agencies, and reporting entities. These costs will be a function of the number of additional events reportable as a result of these amendments and the number of data elements required to be submitted for each additional reportable event.[821]

a. For Platforms and Registered Clearing Agencies

The Commission believes that platforms and registered clearing agencies, when carrying out duties to report security-based swaps, will generally incur the same infrastructure costs that reporting sides face. Like a reporting side, a platform or registered clearing agency must: (1) Develop a transaction processing system; (2) implement a reporting mechanism; and (3) establish an appropriate compliance program and support for the operation of the transaction processing system.[822] Once platforms and registered clearing agencies have established the infrastructure to report security-based swap transactions, reportable events will be reported through electronic means and the marginal cost of reporting an additional transaction once the infrastructure to support the reporting function has been established should be *de minimis.* The Commission continues to estimate that there will be ten platforms and four registered clearing agencies that will incur duties to report security-based swap transactions under the amendments to Rule 901 adopted herein.

For platforms, the costs of reporting infrastructure consist of start-up costs in the first year and ongoing costs each year thereafter. For each platform, the estimated start-up costs include: (1) $102,000 for the initial set-up of the reporting infrastructure to carry out duties under Rule 901;[823] (2) $200,000 for establishing connectivity to a registered SDR;[824] (3) $49,000 for developing, testing, and supporting a reporting mechanism for security-based swap transactions;[825] (4) $77,000 for

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[817] 15 U.S.C. 78m(n)(5)(F).

[818] 17 CFR 240.13n–4(b)(8) and 240.13n–9.

[819] *See supra* note 6.

[820] *See supra* note 7.

[821] This release considers only the events that must be reported as a result of the amendments to Rule 901 being adopted today. In the Regulation SBSR Adopting Release, the Commission estimated the number of reportable events that will result from the rules adopted in that release and the associated costs. *See generally* 80 FR at 14700–704.

[822] *See id.* at 14701.

[823] This estimate is based on the following: [((Sr. Programmer (160 hours) at $303 per hour) + (Sr. Systems Analyst (160 hours) at $260 per hour) + (Compliance Manager (10 hours) at $283 per hour) + (Director of Compliance (5 hours) at $446 per hour) + (Compliance Attorney (20 hours) at $334 per hour))] = approximately $102,000 per platform. All hourly cost figures are based upon data from SIFMA's Management & Professional Earnings in the Securities Industry 2013 (modified by Commission staff to account for an 1,800-hour work-year and multiplied by 5.35 to account for bonuses, firm size, employee benefits, and overhead). *See also* Regulation SBSR Proposed Amendments Release, 80 FR at 14775–76.

[824] The Commission derived the total estimated expense from the following: ($100,000 hardware- and software related expenses, including necessary backup and redundancy, per SDR connection) × (2 SDR connections per platform) = $200,000 per platform. *See also* Regulation SBSR Proposed Amendments Release, 80 FR at 14776.

[825] This figure is calculated as follows: [((Sr. Programmer (80 hours) at $303 per hour) + (Sr.

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order management costs;[826] (5) $1,000 for data storage costs;[827] (6) $54,000 for designing and implementing an appropriate compliance and support program;[828] and (7) $38,500 for maintaining the compliance and support program.[829] Therefore, the Commission estimates total start-up costs of $521,500 per platform and $5,215,000 for all platforms.[830]

The Commission estimates that the amendments to Rule 901 being adopted today also will require each platform to incur the following ongoing costs: (1) $200,000 for maintaining connectivity to a registered SDR;[831] (2) $77,000 for order management costs; (3) $1,000 for data storage costs; and (4) $38,500 for maintaining its compliance and support program. Therefore, the total estimated ongoing cost per year is $316,500 per platform, and $3,165,000 for all platforms.[832]

The Commission estimates that a registered clearing agency will have the same reporting infrastructure cost components as a platform, except that the costs to a registered clearing agency will be marginally higher because Rule 901(e)(1)(ii), as adopted herein, imposes a burden on registered clearing agencies that does not apply to platforms.[833] Although a registered clearing agency might not otherwise establish connectivity to an alpha SDR, the registered clearing agency will have to establish connectivity to alpha SDRs to comply with new Rule 901(e)(1)(ii). Accordingly, the Commission estimates that each registered clearing agency will connect to four registered SDRs.[834]

For each registered clearing agency, the estimated start-up costs consist of: (1) $102,000 for the initial setting-up of the reporting infrastructure to carry out duties under Rule 901; (2) $400,000 for establishing connectivity to a registered SDR;[835] (3) $49,000 for developing, testing, and supporting a reporting mechanism for security-based swap transactions; (4) $77,000 for order management costs; (5) $1,000 for data storage costs; (6) $54,000 for designing and implementing an appropriate compliance and support program; and (7) $38,500 for maintaining its compliance and support program. Therefore, the total estimated start-up cost is $721,500 per registered clearing agency and $2,886,000 in aggregate for all registered clearing agencies.[836]

For each registered clearing agency, the ongoing estimated annual costs consist of: (1) $400,000 for maintaining connectivity to a registered SDR;[837] (2) $77,000 for order management costs; (3) $1,000 for data storage costs; and (4) $38,500 for maintaining its compliance and support program. Therefore, the Commission estimates the ongoing cost per year as $516,500 per registered clearing agency and $2,066,000 for all registered clearing agencies.[838]

The Commission previously estimated, using available transaction data from TIW, that there will be approximately 3 million transaction events per year related to security-based swaps, including the execution of new transactions and various types of life cycle events.[839] The Commission also estimated that Rule 901(a), as adopted in the Regulation SBSR Adopting Release, will require approximately 2 million of those events to be reported under Regulation SBSR.[840] In the Regulation SBSR Proposed Amendments Release, the Commission further estimated that the proposed amendments to Rule 901 would subject another 1 million events to a reporting requirement. This estimate of 1 million reportable events included platform-executed security-based swaps that will be submitted to clearing, all clearing transactions, and all life cycle events associated with such transactions. Specifically, the Commission estimates that platforms will be responsible for the reporting of approximately 120,000 of the 1 million additional reportable events per year.[841] Since a platform must report only the security-based swaps executed on the platform that will be submitted to clearing, the Commission estimates that essentially all 120,000 platform-executed alphas will be terminated. The Commission estimates that there will be approximately 760,000 reportable events per year that are clearing transactions or life cycle events associated with clearing transactions.[842]

Systems Analyst (80 hours) at $260 per hour) + (Compliance Manager (5 hours) at $283 per hour) + (Director of Compliance (2 hours) at $446 per hour) + (Compliance Attorney (5 hours) at $334 per hour))] = approximately $49,000 per platform. *See also* Regulation SBSR Proposed Amendments Release, 80 FR at 14776.

[826] This estimate is based on the following: [((Sr. Programmer (32 hours) at $303 per hour) + (Sr. Systems Analyst (32 hours) at $260 per hour) + (Compliance Manager (60 hours) at $283 per hour) + (Compliance Clerk (240 hours) at $64 per hour) + (Director of Compliance (24 hours) at $446 per hour) + (Compliance Attorney (48 hours) at $334 per hour)))] = approximately $77,000 per platform. *See also* Regulation SBSR Proposed Amendments Release, 80 FR at 14776.

[827] This estimate is calculated as follows: [$250/gigabyte of storage capacity × (4 gigabytes of storage)] = $1,000 per platform. *See also* Regulation SBSR Proposed Amendments Release, 80 FR at 14776.

[828] This figure is calculated as follows: [((Sr. Programmer (100 hours) at $303 per hour) + (Sr. Systems Analyst (40 hours) at $260 per hour) + (Compliance Manager (20 hours) at $283 per hour) + (Director of Compliance (10 hours) at $446 per hour) + (Compliance Attorney (10 hours) at $334 per hour)] = approximately $54,000 per platform. *See also* Regulation SBSR Proposed Amendments Release, 80 FR at 14776.

[829] This figure is calculated as follows: [((Sr. Programmer (16 hours) at $303 per hour) + (Sr. Systems Analyst (16 hours) at $260 per hour) + (Compliance Manager (30 hours) at $283 per hour) + (Compliance Clerk (120 hours) at $64 per hour) + (Director of Compliance (12 hours) at $446 per hour) + (Compliance Attorney (24 hours) at $334 per hour)] = approximately $38,500 per platform. *See also* Regulation SBSR Proposed Amendments Release, 80 FR at 14776.

[830] For each platform, the start-up cost is obtained by summing up its components = $102,000 + $200,000 + $49,000 + $77,000 + $1,000 + $54,000 + $38,500 = $521,500. The start-up cost for all platforms = 10 platforms × $521,500 = $5,215,000.

[831] For each platform, the Commission estimates the cost of maintaining connectivity to an SDR to be the same as the cost of establishing connectivity to a registered SDR.

[832] For each platform, the on-going cost per year is obtained by summing up its components = $200,000 + $77,000 + $1,000 + $38,500 = $316,500. The ongoing cost per year for all platforms = 10 platforms × $316,500 = $3,165,000.

[833] Rule 901(e)(1)(ii) requires a registered clearing agency to report whether or not it has accepted an alpha for clearing to the alpha SDR. *See supra* Section III(G).

[834] *Cf. supra* Section XII(A)(1)(a) (estimating that each platform will connect to only two registered SDRs).

[835] The Commission derived the total estimated expense for registered clearing agencies as ($100,000 hardware- and software-related expenses, including necessary backup and redundancy, per SDR connection) × (4 SDR connections per registered clearing agency) = $400,000 per registered clearing agency. *See* Regulation SBSR Proposed Amendments Release, 80 FR at 14776 (estimating the hardware- and software-related expenses per SDR connection at $100,000).

[836] For each registered clearing agency, the start-up cost is obtained by summing up its components = $102,000 + $400,000 + $49,000 + $77,000 + $1,000 + $54,000 + $38,500 = $683,000. The start-up cost for all registered clearing agencies = 4 registered clearing agencies × $721,500 = $2,886,000. These figures represent an estimate of the costs to a registered clearing agency to be fully onboarded with a registered SDR to allow reporting of all of the primary and secondary trade information associated with security-based swaps, as reporting sides are required to report. To the extent that a registered clearing agency must report to a registered SDR only alpha clearing dispositions and not entire transaction reports, the cost incurred by the clearing agency to carry out such reporting could be less. Regulation SBSR does not require full onboarding with an alpha SDR to report the limited number of data elements necessary to convey whether or not the clearing agency has accepted a particular alpha for clearing.

[837] The Commission estimates that a registered clearing agency's cost of maintaining connectivity to an SDR is the same as the registered clearing agency's cost of establishing connectivity to an SDR.

[838] The ongoing cost per year is obtained by summing up its components = $400,000 + $77,000 + $1,000 + $38,500 = $516,500. The ongoing cost per year for all registered clearing agencies = 4 registered clearing agencies × $516,500 = $2,066,000.

[839] *See* Regulation SBSR Proposed Amendments Release, 80 FR at 14776.

[840] *See id.*

[841] *See supra* Section XI(B)(2)(b)(iv).

[842] *See id.*

The Commission estimates that platforms will be responsible for reporting approximately 120,000 security-based swaps per year, at an annual cost of approximately $45,300 or $4,530 per platform,[843] and that registered clearing agencies will be responsible for reporting approximately 760,000 reportable events at an annual cost of approximately $286,900 or $71,725 per registered clearing agency.[844] The Commission believes that all reportable events that will be reported by platforms and registered clearing agencies pursuant to the amendments to Rule 901(a) will be reported through electronic means.

In the Regulation SBSR Adopting Release, the Commission stated that, to the extent that security-based swaps become more standardized and trade more frequently on electronic platforms (rather than manually), the act of reporting transactions to a registered SDR should become less costly.[845] Together, these trends are likely to reduce the number of transactions that necessitate the manual capture of bespoke data elements, which is likely to take more time and be more expensive than electronic capture of standardized transactions. New Rules 901(a)(1) and (a)(2)(i), respectively, assign reporting duties to clearing transactions and platform-executed security-based swaps that will be submitted to clearing. To the extent that registered clearing agencies make standardized security-based swaps available for clearing and platforms make standardized security-based swaps available for trading, the reporting of transactions covered by Rules 901(a)(1) and (a)(2)(i) should be less costly on average than the reporting of bespoke security-based swaps.

One commenter argued that the incremental costs of assigning the reporting obligation to the alpha reporting side would be small compared to the costs associated with registered clearing agencies incurring the reporting duty and having to establish connectivity to alpha SDRs.[846] The Commission estimates that a registered clearing agency will connect to four registered SDRs as a result of Rule 901(e)(1)(ii),[847] but that, in the absence of this rule, a registered clearing agency, like a platform, would connect to only two registered SDRs.[848] Thus, the Commission estimates that a registered clearing agency has to connect to two additional alpha SDRs as a result of new Rule 901(e)(1)(ii). The estimated cost of establishing connectivity to two SDRs is $200,000, and the estimated annual cost of maintaining connectivity to two SDRs is $200,000.[849] The estimated aggregate cost of establishing connectivity to alpha SDRs is $800,000, and the estimated aggregate annual cost of maintaining connectivity to alpha SDRs is $800,000. The Commission estimates that the costs to the alpha reporting side of reporting the initial alpha transaction are an upper bound estimate of the costs of assigning the duty to report clearing dispositions of alphas to the alpha reporting side.[850] To estimate the costs to the alpha reporting side of reporting the initial alpha transaction, the Commission assumes that the total annual number of platform-executed alpha transactions that will be submitted for clearing is 120,000.[851] The Commission estimates the costs to the alpha reporting sides of reporting the initial alpha transactions to be the same as the platforms' costs of reporting the 120,000 platform-executed alpha transactions. Thus, the aggregate reporting costs are approximately $45,300 per year,[852] which represent an upper bound estimate of the costs of assigning the reporting obligation to the alpha reporting side.

The Commission recognizes that its estimate of the costs that an alpha reporting side would incur to report whether a security-based swap was accepted for clearing are lower than its estimate of the cost that a registered clearing agency would incur in order to establish connectivity to alpha SDRs to meet the same regulatory obligation under Rule 901(e)(1)(ii). Nevertheless, the Commission is adopting Rule 901(e)(1)(ii) as proposed because, as explained above, this approach is likely to efficiently support data quality at registered SDRs. Accordingly, the Commission believes that the approach reflected in newly adopted Rule 901(e)(1)(ii) is appropriate even in light of the costs. The Commission notes that existing Rule 901(c)(6) requires reporting of an indication whether the direct counterparties intend that a security-based swap will be submitted to clearing so that this information will appear in the transaction records of the alpha SDR. The Commission believes that requiring reporting to the alpha SDR of whether or not a registered clearing agency accepts the alpha for clearing will facilitate the Commission's ability to measure outstanding bilateral exposures, including exposures to registered clearing agencies.

Moreover, the Commission's determination that the clearing agency to which the security-based swap is submitted for clearing should be required to report the disposition of the alpha rather than the alpha reporting side (or a platform, in the case of a platform-executed alpha) is designed to improve the integrity of information about cleared security-based swaps. The Commission believes that centralizing responsibility for reporting this information in a small number of registered clearing agencies rather than a larger number of alpha reporting sides and platforms minimizes the likelihood of orphan alphas. The adopted approach should facilitate the ability of alpha SDRs to match clearing disposition reports with the original alpha transaction reports and help the Commission to obtain a more accurate view of the exposures of counterparties that intended to clear transactions. A more accurate view of the exposures of counterparties will enable the Commission to conduct robust monitoring of the security-based swap market for potential risks to financial markets and financial market participants.[853]

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[843] The Commission estimates: ((120,000 × 0.005 hours per transaction)/(10 platforms)) = 60 hours per platform, or 600 total hours. The Commission further estimates the total cost to be: [((Compliance Clerk (30 hours) at $64 per hour) + (Sr. Computer Operator (30 hours) at $87 per hour)) × (10 platforms)] = approximately $45,300, or $4,530 per platform. *See also* Regulation SBSR Proposed Amendments Release, 80 FR at 14777.

[844] The Commission estimates: ((760,000 × 0.005 hours per transaction)/(4 registered clearing agencies)) = 950 hours per registered clearing agency, or 3,800 total hours. The Commission further estimates the total cost to be: [((Compliance Clerk (475 hours) at $64 per hour) + (Sr. Computer Operator (475 hours) at $87 per hour)) × (4 registered clearing agencies)] = $286,900, or $71,725 per registered clearing agency. *See also* Regulation SBSR Proposed Amendments Release, 80 FR at 14777, which estimates the time taken to process a transaction at 0.005 hours, the hourly rate of a Compliance Clerk at $64 per hour, and the hourly rate of a Sr. Computer Operator at $87 per hour.

[845] *See* 80 FR at 14703.

[846] *See supra* Section III(G).

[847] *See supra* Section XII(A)(1)(a).

[848] *See id.*

[849] The cost of establishing SDR connectivity is estimated as ($100,000 hardware- and software-related expenses, including necessary backup and redundancy, per SDR connection) × (2 SDR connections per registered clearing agency) = $200,000 per registered clearing agency. *See also* Regulation SBSR Adopting Release, 80 FR at 14701. The Commission estimates that a registered clearing agency's cost of maintaining connectivity to two alpha SDRs is the same as the registered clearing agency's cost of establishing connectivity to two alpha SDRs. These costs do not represent new compliance costs. They are part of the start-up and ongoing costs incurred by a registered clearing agency to comply with the amendments to Rule 901 adopted today and discussed in Section XII(A)(1)(a), *supra*. The estimated aggregate cost of establishing connectivity to alpha SDRs is ($200,000 alpha SDR connectivity cost per registered clearing agency) × (4 registered clearing agencies) = $800,000. The estimated aggregate annual cost of maintaining connectivity to alpha SDRs is ($200,000 alpha SDR connectivity maintenance cost per registered clearing agency) × (4 registered clearing agencies) = $800,000.

[850] The costs of reporting the initial alpha trade form an upper bound estimate because the initial alpha trade report likely requires more data elements to be captured and transmitted than would a report of whether the alpha trade has been accepted for clearing.

[851] *See supra* Section XII(A)(1)(a).

[852] *See id.*

Furthermore, Rule 901(e)(1)(ii) is consistent with the Commission's approach of assigning the reporting obligation for a transaction to the person with the most complete and efficient access to the required information at the point of creation. The registered clearing agency determines whether to accept an alpha for clearing and controls the precise moment when the transaction is cleared; the Commission believes, therefore, that the clearing agency is best placed to report the result of its decision. If the alpha reporting side were required to report whether or not the alpha has been accepted for clearing, it would first need to learn this information from the registered clearing agency.[854] As the Commission noted in Section III(B), *supra,* a rule that required reporting by a person who lacks direct access, at the time of creation, to the information that must be reported would increase the risks of data discrepancies, errors, or delays. Accordingly, for the same reasons that the Commission is assigning to registered clearing agencies the duty to report all clearing transactions, the Commission also believes that it is more efficient to require a registered clearing agency to report to the alpha SDR whether or not the clearing agency has accepted the alpha for clearing.

b. For Platforms and Reporting Sides of Alphas

Under new Rule 901(a)(3), a person who has a duty to report an alpha transaction also is required to promptly provide the registered clearing agency with the transaction ID of the alpha transaction and the identity of the registered SDR to which the transaction will be or has been reported.

Reporting sides and platforms are likely already to have in place the infrastructure needed to report security-based swaps to a registered clearing agency, as voluntary clearing of standardized single-name CDS has become a significant feature of the existing security-based swap market in the United States. Furthermore, as additional platforms enter the security-based swap market, it is likely that they also will seek to establish connectivity to one or more registered clearing agencies, as there are market incentives to clear platform-executed security-based swaps and platforms will likely seek to offer their participants the ability to transmit information about platform-executed transactions directly to a clearing agency. Thus, the Commission does not believe that new Rule 901(a)(3) will require additional infrastructure or connectivity that otherwise would not exist.

However, Rule 901(a)(3) will require persons with the duty to report alphas to provide two additional data elements—the transaction ID of the alpha and the name of the alpha SDR—to the registered clearing agency. The Commission believes that persons who submit security-based swap transactions to registered clearing agencies will comply with Rule 901(a)(3) by including these two data elements along with all of the other transaction data submitted to the clearing agency. The Commission estimates that the one-time cost for developing the ability to report these two data elements will be $2,815 per reporting person, and the additional one-time burden related to the implementation of a reporting mechanism for these two data elements will be $1,689 per reporting person.[855] The Commission believes that the additional ongoing cost related to the development of the ability to capture the relevant transaction information will be $2,815 per reporting person and the additional ongoing burden related to the maintenance of the reporting mechanism will be $563 per reporting person.[856]

c. Total Costs of Platforms, Registered Clearing Agencies, and Reporting Sides Relating to Amendments to Rule 901

Summing these costs,[857] the Commission estimates that the initial, first-year costs of complying with the amendments to Rule 901 (including the initial reporting and the reporting of any life cycle events) will be $5,260,300, which corresponds to $526,030 per platform.[858] The Commission estimates that the ongoing aggregate annual costs, after the first year, of complying with the amendments to Rule 901 (including the initial reporting and the reporting of any life cycle events) will be $3,210,300, which corresponds to $321,030 per platform.[859]

For registered clearing agencies, the Commission estimates that the initial, first-year costs of complying with the amendments to Rule 901 (including the initial reporting and the reporting of any life cycle events) will be $3,172,900, which corresponds to $793,225 per registered clearing agency.[860] The Commission estimates that the ongoing aggregate annual costs, after the first year, of complying with the amendments to Rule 901 (including the initial reporting and the reporting of any life cycle events) will be $2,352,900, which corresponds to $588,225 per registered clearing agency.[861]

For compliance with new Rule 901(a)(3), the Commission estimates that the initial, first-year costs of complying will be $1,396,240, which corresponds to $4,504 per respondent.[862] The

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[853] *See* Regulation SBSR Adopting Release 80 FR at 14700.

[854] The commenter who advocated that the duty to report whether or not the transaction has been accepted for clearing should be given to the reporting side of the alpha acknowledged that the alpha reporting side must rely on the clearing agency to provide information about the disposition of any transaction submitted to clearing. *See* LCH.Clearnet Letter at 9–10.

[855] The Commission estimates the cost of developing the ability to capture the alpha's transaction ID and the alpha SDR as: [(Sr. Programmer (5 hours at $303 per hour) + Sr. Systems Analyst (5 hours) at $260 per hour) = $2,815 per platform or reporting side. The Commission estimates the cost of implementing the reporting mechanism as: (Sr. Programmer (3 hours) at $303 per hour + Sr. Systems Analyst (3 hours) at $260 per hour) = $1,689 per platform or reporting side.

[856] The Commission estimates the additional ongoing development cost as (Sr. Programmer (5 hours at $303 per hour) + Sr. Systems Analyst (5 hours at $260 per hour)) = $2,815 per platform or reporting side. The Commission estimates the ongoing maintenance cost as (Sr. Programmer (1 hour at $303 per hour) + Sr. Systems Analyst (1 hour at $260 per hour)) = $563 per platform or reporting side.

[857] In the Regulation SBSR Proposed Amendments Release, platforms' initial, first-year costs and ongoing aggregate annual costs included costs incurred under Rule 901(a)(3). In this release, platforms' initial, first-year costs and ongoing aggregate annual costs do not include costs incurred under Rule 901(a)(3). Instead, platforms' Rule 901(a)(3) costs have been added to the Rule 901(a)(3) costs of the 300 reporting sides to estimate the initial, first-year and ongoing aggregate annual costs of Rule 901(a)(3) for 300 reporting sides and 10 platforms.

[858] This estimate is based on the following: (($102,000 + $200,000 + $49,000 + $77,000 + $54,000 + $1,000 + $38,500 + $4,530) × (10 platforms)) = $5,260,300 which corresponds to $526,030 per platform.

[859] This estimate is based on the following: (($200,000 + $77,000 + $1,000 + $38,500 + $4,530) × (10 platforms)) = $3,210,300, or $321,030 per platform.

[860] This estimate is based on the following: (($102,000 + $400,000 + $49,000 + $77,000 + $54,000 + $1,000 + $38,500 + $71,725) × (4 registered clearing agencies)) = $3,172,900, which corresponds to $793,225 per registered clearing agency.

[861] This estimate is based on the following: (($400,000 + $77,000 + $1,000 + $38,500 + $71,725) × (4 registered clearing agencies)) = $2,352,900, or $588,225 per registered clearing agency.

[862] This estimate is based on the following: ($2,815 + $1,689) × 310 (300 reporting sides + 10 platforms)) = $1,396,240, which corresponds to

Commission estimates that the ongoing aggregate annual costs, after the first year, of complying with Rule 901(a)(3) will be $1,047,180, which corresponds to $3,378 per respondent.[863]

d. Reporting by Unregistered Persons

As noted in Section IX(G), *supra*, the amendments to existing Rule 901(a)(2)(ii)(E) that are being adopted today expand the reporting hierarchy to assign the duty to report additional cross-border transactions when there is no registered person on either side. As under existing Rule 901, the reporting side, as determined by the reporting hierarchy, is required to submit the information required by Rule 901.

Under newly adopted Rule 901(a)(2)(ii)(E)(*2*), in a transaction between an unregistered U.S. person and an unregistered foreign dealing entity that is engaging in ANE activity, the sides are required to select which side is the reporting side. Also under Rule 901(a)(2)(ii)(E)(*2*), if both sides are unregistered non-U.S. persons and both are engaging in ANE activity, the sides would be required to select the reporting side. In both scenarios, both sides would be subject to Rule 908(b) and thus the Commission could impose reporting duties on either side.

Newly adopted Rule 901(a)(2)(ii)(E)(*3*) addresses the scenario where one side is subject to Rule 908(b) and the other side is not—*i.e.*, one side includes only unregistered non-U.S. persons that do not engage in any ANE activity. When the other side includes an unregistered U.S. person or an unregistered foreign dealer that *is* engaging in ANE activity, the side with the unregistered U.S. person or the unregistered foreign dealing entity would be the reporting side.[864]

In the Regulation SBSR Adopting Release,[865] the Commission estimated that 300 respondents will incur reporting duties under Regulation SBSR, of which 50 are likely to register as security-based swap dealers and five are likely to register as major security-based swap market participants. Unregistered persons covered by new Rules 901(a)(2)(ii)(E)(*2*) and (*3*) are already included in the remaining subset of 245 respondents that are not likely to register as security-based swap dealers or major security-based swap participants. Because the Commission had already accounted for the programmatic costs of building reporting infrastructure and reporting security-based swap transactions incurred by these 300 respondents in the Regulation SBSR Adopting Release,[866] Rules 901(a)(2)(ii)(E)(*2*) and (*3*) will not result in additional programmatic costs associated with reporting infrastructure or transaction reporting. Two commenters noted that requiring the reporting of ANE transactions would place burdens on unregistered entities that do not have reporting infrastructure in place and would be compelled to engage third-party providers to report transactions.[867] The Commission acknowledges that the reporting of ANE transactions will place burdens on unregistered entities, but in only a limited number of cases. The Commission estimates that the initial aggregate annual costs associated with Rule 901 will be approximately $2,096,000, which corresponds to approximately $524,000 per unregistered entity.[868] The Commission estimates that the ongoing aggregate annual costs associated with Rule 901 will be approximately $1,276,000, which corresponds to approximately $319,000 per unregistered entity.[869] As discussed earlier, these programmatic costs are part of the programmatic costs associated with Rule 901 that were accounted for in the Regulation SBSR Adopting Release. Unregistered foreign dealing entities could fulfil their reporting obligations by incurring the programmatic costs of building reporting infrastructure and reporting security-based swap transactions. Alternatively, these entities could engage with third-party service providers to carry out any reporting duties incurred under Regulation SBSR.[870] The Commission disagrees with the commenters that unregistered entities would use third-party service providers without considering alternatives. Though the Commission does not have specific information on the pricing of third-party reporting services on which to base estimates of the cost of engaging third-parties to provide reporting services, the Commission notes that unregistered entities will likely choose the method of compliance that they deem to be most cost efficient. Thus, the Commission assumes that unregistered entities would engage third-party service providers only if they provide services at costs less than the programmatic costs of Rule 901 estimated above.

Under new Rule 901(a)(2)(ii)(E)(*4*), a registered broker-dealer would incur the duty to report a security-based swap that is effected by or through that broker-dealer only when neither side includes a person that falls within Rule 908(b)(5). The Commission estimates that a maximum of 20 registered broker-dealers, excluding registered SB SEFs, will incur this reporting duty and will report 540 security-based swap transactions per year. Unlike the unregistered counterparties covered by Rules 901(a)(2)(ii)(E)(*2*) and (*3*), these 20 registered broker-dealers were not part of the 300 respondents the Commission estimated in the Regulation SBSR Adopting Release. Therefore, by subjecting the 20 registered broker-dealers to Regulation SBSR, new Rule 901(a)(2)(ii)(E)(*4*) adds new programmatic costs associated with reporting infrastructure.

The Commission estimated the costs of reporting on a per-entity basis in the Regulation SBSR Adopting Release and has no reason to believe that these per-entity costs are substantially different

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$4,504 per respondent. In the Regulation SBSR Proposed Amendments Release, the estimate only included the one-time cost related to the development of the ability to capture the relevant transaction information ($2,815). The estimation has been revised to also include the one-time cost of implementing a reporting mechanism for the transaction information ($1,689).

[863] This estimate is based on the following: (($2,815 + $563) × 310 (300 reporting sides + 10 platforms)) = $1,047,180, or $3,378 per respondent. In the Regulation SBSR Proposed Amendments Release, the estimate only included the ongoing cost related to the development of the ability to capture the relevant transaction information ($2,815). The estimation has been revised to also include the ongoing cost of implementing a reporting mechanism for the transaction information ($563).

[864] While Rules 901(a)(2)(ii)(E)(*2*)–(*3*) admit the possibility that some of these unregistered persons are U.S. persons, the Commission does not expect unregistered U.S. persons to be responsible for reporting a significant amount of additional transaction under Rules 901(a)(2)(ii)(E)(*2*)–(*3*). In current market practice, larger, more sophisticated participants assume reporting duties. As a result, in cases where an unregistered U.S. person and a non-U.S. person engaged in dealing activity in the United States select the reporting side, the reporting duty is likely to be assigned to the non-U.S. person. *See supra* Section IX(G)(2)(a).

[865] *See* 80 FR at 14674.

[866] *See id.* at 14701–702.

[867] *See* ISDA I at 11; SIFMA/FSR Letter at 13.

[868] The initial cost estimates are based on the following: $524,000 × 4 unregistered entities = $2,096,000, which corresponds to $524,000 per unregistered entity. *See* Regulation SBSR Adopting Release, 80 FR at 14702. The four unregistered entities are the estimated number of unregistered foreign dealing entities that will engage in ANE activity. *See supra* Section II(A)(4)(d). The Commission assumes that unregistered U.S. persons that fall under Rules 901(a)(2)(ii)(E)(*2*) and (*3*) will not assume reporting duties. *See supra* Section IX(G)(2)(a).

[869] The ongoing cost estimates are based on the following: $319,000 × 4 unregistered entities = $1,276,000, which corresponds to $319,000 per unregistered entity. *See id.* for a discussion of the assumptions underlying the calculations.

[870] The Commission does not have data with which to estimate the costs of using third-party service providers to carry out reporting duties incurred under Regulation SBSR. The two commenters did not provide such cost estimates in their letters. *See* ISDA I at 11; SIFMA/FSR Letter at 13).

for different types of entities.[871] Therefore, the Commission is applying these per-entity costs to estimate the Rule 901 programmatic costs for the 20 registered broker-dealers.[872]

For a registered broker-dealer, the cost of reporting infrastructure consists of start-up cost in the first year and, thereafter, ongoing annual costs. For each registered broker-dealer, the start-up cost is broken down into: (1) $102,000 for the initial set-up of the reporting infrastructure to carry out duties under Rule 901; (2) $200,000 for establishing connectivity to a registered SDR; (3) $49,000 for developing, testing, and supporting a reporting mechanism for security-based swap transactions; (4) $77,000 for order management costs; (5) $1,000 for data storage costs; (6) $54,000 for designing and implementing an appropriate compliance and support program; and (7) $38,500 for maintaining the compliance and support program.[873] Therefore, the total start-up cost is $521,500 per registered broker-dealer and $10,430,000 in aggregate, across all registered broker-dealers.[874]

For each registered broker-dealer, the ongoing annual cost consists of: (1) $200,000 for maintaining connectivity to a registered SDR; [875] (2) $77,000 for order management costs; (3) $1,000 for data storage costs; and (4) $38,500 for maintaining its compliance and support program. Therefore, the ongoing cost per year is $316,500 per registered broker-dealer, and $6,330,000 for all registered broker-dealers.[876] In the Regulation SBSR Adopting Release,[877] the Commission estimated that there will be 3 million reportable events per year under Rule 901. Of the 3 million events, 2 million are not clearing transactions. The transactions that will be reported by registered broker-dealers as a result of new Rule 901(a)(2)(ii)(E)(*4*) were assessed by the Commission as part of the 2 million non-clearing transactions. The Commission already accounted for the cost of reporting the 2 million non-clearing transactions in the Regulation SBSR Adopting Release.

2. Amendments to Rule 905(a)

The amendments to Rule 905(a) adopted herein provide that any counterparty or other person having a duty to report a security-based swap that discovers an error in information previously reported pursuant to Regulation SBSR must correct such error in accordance with the procedures laid out in Rule 905(a). As the Commission noted in the Regulation SBSR Adopting Release, requiring participants to promptly correct erroneous transaction information should help ensure that the Commission and other relevant authorities have an accurate view of the risks in the security-based swap market.

In the Regulation SBSR Adopting Release, the Commission estimated that Rule 905(a) will impose an initial, one-time burden associated with designing and building a reporting side's reporting system to be capable of submitting amended security-based swap transaction information to a registered SDR.[878] The Commission stated its belief that designing and building appropriate reporting system functionality to comply with Rule 905(a)(2) will be a component of, and represent an incremental "add-on" to, the cost to build a reporting system and develop a compliance function as required under Rule 901.[879] Specifically, the Commission estimated that, based on discussions with industry participants, the incremental burden will be equal to 5% of the one-time and annual burdens associated with designing and building a reporting system that is in compliance with Rule 901, plus 10% of the corresponding one-time and annual burdens associated with developing the reporting side's overall compliance program required under Rule 901.[880] This estimate was based on similar calculations contained in the Regulation SBSR Proposing Release,[881] updated to reflect new estimates relating to the number of reportable events and the number of reporting sides.[882]

The Commission continues to believe that the above methodology is applicable to error reporting by platforms and registered clearing agencies under the amendment to Rule 905(a). Thus, for these new respondents, the Commission estimates that Rule 905(a) will impose an initial (first-year) aggregate cost of $165,550, or $11,825 per respondent,[883] and an ongoing aggregate annualized cost of $55,650, which is $3,975 per respondent.[884]

The Commission estimates that four unregistered foreign dealing entities will engage in ANE activity and incur a duty to report as a result of new Rules 901(a)(2)(ii)(E)(*2*) and (*3*).[885] These unregistered persons also will incur costs associated with error reporting under Rule 905. As noted in Section XII(A)(1)(d), *supra*, these unregistered persons are part of the subset of 300 respondents that were identified in the Regulation SBSR Adopting Release as not likely to register as security-based swap dealers or major security-based swap participants. Because the Commission already accounted for the programmatic costs of building and maintaining error reporting capabilities incurred by these 300 respondents in the Regulation SBSR Adopting Release,[886] the amendments to Rule 905(a) will not result in additional programmatic costs for the four unregistered persons.

The Commission estimates that 20 registered broker-dealers, excluding SB SEFs, will incur a duty to report security-based swap transactions because of new Rule

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[871] *See id.*

[872] One commenter argued that Rule 901(a)(2)(ii)(E)(*4*) "would create a disproportionate burden on registered broker-dealers relative to the small percentage of the market that these transactions compromise." SIFMA/FSR Letter at 14. The Commission notes that many registered broker-dealers may already have order management systems in place to facilitate voluntary reporting of security-based swap transactions or clearing activity. As a result, any additional costs related to systems and infrastructure will be limited to those broker-dealers that either invest in new systems or must upgrade existing systems to meet minimum requirements for reporting. To the extent that the cost estimates discussed here do not take this cost limiting fact into account, they are an upper bound for the estimated costs. *See* Regulation SBSR Adopting Release, 80 FR at 14701.

[873] *See supra* Section XII(A)(1)(a).

[874] For each registered broker-dealer, the start-up cost is obtained by summing up its components = $102,000 + $200,000 + $49,000 + $77,000 + $1,000 + $54,000 + $38,500 = $521,500. The start-up cost for all registered broker-dealers = 20 registered broker-dealers × $521,500 = $10,430,000.

[875] *See supra* Section XII(A)(1)(a).

[876] For each registered broker-dealer, the on-going cost per year is obtained by summing up its components = $200,000 + $77,000 + $1,000 + $38,500 = $316,500. The on-going cost per year for all registered broker-dealers is estimated to be (20 registered broker-dealers × $316,500) = $6,330,000.

[877] *See* Regulation SBSR Adopting Release, 80 FR at 14676.

[878] *See* 80 FR at 14714.

[879] *See id.*

[880] *See id.*

[881] *See* 75 FR at 75254.

[882] *See* Regulation SBSR Adopting Release, 80 FR at 14701–702.

[883] *See* Regulation SBSR Proposing Release, 75 FR at 75254–55. This figure is calculated as follows: [((($49,000 for one-time development of reporting system) × (0.05)) + (($2,500 annual maintenance of reporting system) × (0.05)) + (($54,000 one-time compliance program development) × (0.1)) + (($38,500 annual support of compliance program) × (0.1))) × 14 reporting entities (10 platforms + 4 registered clearing agencies)] = $165,550, which is $11,825 per platform or registered clearing agency.

[884] *See* Regulation SBSR Proposing Release, 75 FR at 75254–55. This figure is calculated as follows: [(($2,500 annual maintenance of reporting system) × (0.05)) + (($38,500 annual support of compliance program) × (0.1))) × 14 reporting entities (10 platforms + 4 registered clearing agencies)] = $55,650, which is $3,975 per platform or registered clearing agency.

[885] *See supra* Section II(A)(4)(d) for a discussion of how these dealing entities are identified in the TIW data.

[886] *See* 80 FR at 14714.

901(a)(2)(ii)(E)(*4*).[887] Thus, these registered broker-dealers are subject to the amendment to Rule 905(a) adopted herein and will incur costs associated with error reporting.

The Commission continues to believe that the cost estimation methodology previously applied in the Regulation SBSR Adopting Release is applicable to error reporting by registered broker-dealers.[888] Thus, for registered broker-dealers, the Commission estimates that the amendment to Rule 905(a) will impose an initial (first-year) aggregate cost of $236,500, or $11,825 per respondent,[889] and an ongoing aggregate annualized cost of $79,500, or $3,975 per respondent.[890]

Rule 905(a)(1) as amended herein states that, if a person that was not the reporting side for a security-based swap transaction discovers an error in the information reported with respect to such security-based swap, that person shall promptly notify the person having the duty to report the security-based swap of the error. Clients of registered broker-dealers likely will incur costs, because Rule 905(a)(1) requires them to notify registered broker-dealers of errors in transaction reports made by the registered broker-dealers pursuant to Rule 901(a)(2)(ii)(E)(*4*). As stated in Section XII(A)(1)(d), *supra*, the Commission estimates that registered broker-dealers will incur the duty to report 540 security-based swap transactions per year under Rule 901(a)(2)(ii)(E)(*4*). Assuming that each of the 540 transactions is reported in error, the upper bound estimate of the annual cost associated with this obligation is approximately $17,280, which corresponds to roughly $576 per respondent.[891]

3. Amendments to Rule 906(c)

Existing Rule 906(c) requires each participant of a registered SDR that is a registered security-based swap dealer or registered major security-based swap participant to establish, maintain, and enforce written policies and procedures that are reasonably designed to ensure compliance with any security-based swap transaction reporting obligations in a manner consistent with Regulation SBSR. Rule 906(c) also requires each such participant to review and update the required policies and procedures at least annually. The amendment to Rule 906(c) adopted herein extends these same requirements to participants of a registered SDR that are platforms, registered clearing agencies, and registered broker-dealers.

The Commission continues to believe that the cost estimation methodology previously applied in the Regulation SBSR Adopting Release is applicable to the adoption and maintenance of policies and procedures.[892] Thus, for registered clearing agencies and platforms, the Commission estimates that the amendments to Rule 906(c) will impose an initial (first-year) aggregate cost of $1,288,000, or $92,000 per registered clearing agency or platform,[893] and an ongoing aggregate annualized cost of $476,000, or $34,000 per registered clearing agency or platform.[894] In addition, for registered broker-dealers likely to become participants solely as a result of making a report to satisfy an obligation under Rule 901(a)(2)(ii)(E)(*4*) (a "respondent broker-dealer"), the Commission estimates that the amendments to Rule 906(c) will impose an initial (first-year) aggregate cost of $1,840,000, or $92,000 per respondent broker-dealer,[895] and an ongoing aggregate annualized cost of $680,000, or $34,000 per respondent broker-dealer.[896] The Commission does not believe that the amendments to Rule 906(c) will impose any economic costs beyond the paperwork burdens described herein and in Section XI(D)(2)(c), *supra*.

4. Amendments That Subject Additional Cross-Border Security-Based Swaps to Regulation SBSR

a. ANE Transactions Involving Unregistered Entities

New Rule 908(a)(1)(v) provides that any security-based swap transaction connected with a non-U.S. person's security-based swap dealing activity that is arranged, negotiated, or executed by U.S. personnel is subject to regulatory reporting and public dissemination under Regulation SBSR.

Several commenters expressed concern about the complexities and expense of implementing the adopted rules.[897] One commenter stated there would be significant costs associated with reporting because market participants that have already designed and implemented reporting systems based on the CFTC's cross-border guidance and the rules of other jurisdictions would need to modify their systems to comply with the Commission's proposed rules.[898]

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[887] *See supra* Section XII(A)(1)(d).

[888] *See* 80 FR at 14714.

[889] *See* Regulation SBSR Proposing Release, 75 FR at 75254–55. This figure is calculated as follows: [((($49,000 for one-time development of reporting system) × (0.05)) + (($2,500 annual maintenance of reporting system) × (0.05)) + (($54,000 one-time compliance program development) × (0.1)) + (($38,500 annual support of compliance program) × (0.1))) × 20 registered broker-dealers] = $236,500, which is $11,825 per registered broker-dealer.

[890] *See* Regulation SBSR Proposing Release, 75 FR at 75254–55. This figure is calculated as follows: [((($2,500 annual maintenance of reporting system) × (0.05)) + (($38,500 annual support of compliance program) × (0.1))) × 20 registered broker-dealers] = $79,500, which is $3,975 per registered broker-dealer.

[891] These figures are based on the assumption that approximately 540 additional security-based swap transactions per year will have to be reported by registered broker-dealers pursuant to Rule 901(a)(2)(ii)(E)(*4*), and that these trades involve 30 entities with reporting duties. Using cost estimated provided in the Regulation SBSR Adopting Release, if each trade is reported in error, then the aggregate annual cost of error notification is 540 errors × Compliance Clerk at $64 per hour × 0.5 hours per report = $17,280, or $576 per participant. *See* Regulation SBSR Adopting Release, 80 FR at 14714. Salary figures are taken from SIFMA's Management & Professional Earnings in the Securities Industry 2013, modified to account for a 1,800-hour work-week and multiplied by 5.35 to account for bonuses, firm size, employee benefits, and overhead.

[892] *See* Regulation SBSR Adopting Release, 80 FR at 14716.

[893] *See id.* This figure is based on the following: [(($58,000 for one time developing of written policies and procedures) + ($34,000 for annual updates to policies and procedures)) × 14 registered clearing agencies and platforms] = $1,288,000, which is $92,000 per registered clearing agency or platform.

[894] *See* Regulation SBSR Adopting Release, 80 FR at 14716. This figure is based on the following: [($34,000 for annual updates to policies and procedures) × 14 registered clearing agencies and platforms] = $476,000, which is $34,000 per registered clearing agency or platform.

[895] *See* Regulation SBSR Adopting Release, 80 FR at 14716. This figure is based on the following: [(($58,000 for one time developing of written policies and procedures) + ($34,000 for annual updates to policies and procedures)) × 20 respondent broker-dealers] = $1,840,000, which is $92,000 per respondent broker-dealer.

[896] *See* Regulation SBSR Adopting Release, 80 FR at 14716. This figure is based on the following: [($34,000 for annual updates to policies and procedures) × 20 respondent broker-dealers] = $680,000, which is $34,000 per respondent broker-dealer.

[897] *See* IIB Letter at 16 (stating that regulatory reporting of transactions where neither reporting side includes a U.S. person, guaranteed affiliate, or registered security-based swap dealer would come with significant cost); ISDA I at 11 (stating that expanding the reporting requirements to non-U.S. trades would be burdensome and costly); SIFMA–AMG I at 2 (stating that requiring the reporting of transactions that were arranged, negotiated or executed in the United States would increase the transactional burdens on "an already taxed system"); SIFMA/FSR Letter at 12 (taking the view that monitoring for conduct in the United States and building the infrastructure needed for reporting based purely on conduct will be an unnecessary expense for security-based swap market participants since the information being added to the public dissemination stream would not be informative or could give a distorted view of market prices and would result in data at SDRs that has minimal U.S. nexus).

[898] *See* IIB Letter at 16. The commenter stated that, to modify its systems in connection with the U.S. personnel test, a non-U.S. dealing entity (including one operating below the *de minimis* threshold) "would need to install or modify a trade capture system capable of tracking, on a dynamic, trade-by-trade basis, the location of front-office personnel. The non-U.S. SBSD would then need to feed that data into its reporting system and re-code

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The Commission agrees that market participants will incur costs to comply with the reporting requirements of Rule 908(a)(1)(v). However, the Commission notes that all ANE transactions where a U.S. person is on one side as either a direct or indirect counterparty are already subject to regulatory reporting under the rules adopted in the Regulation SBSR Adopting Release. Thus, only a small number of ANE transactions—which the Commission estimates will result in at most 1,080 reportable events per year—will be subject to regulatory reporting as a result of new Rule 908(a)(1)(v); accordingly, the attendant costs of complying with Rule 908(a)(1)(v) will also be relatively small. The Commission understands that market participants may have to incur costs to modify their existing reporting systems to comply with the Commission's rules.[899] However, to the extent that these rules and rules in other jurisdictions require the collection of the same or similar information, the system modification costs will be minimized.[900]

The Commission believes that the reporting and public dissemination of all ANE transactions will provide benefits to the Commission and relevant authorities and to market participants. The Commission also believes that requiring the public dissemination of these transactions could help to increase price competition and price efficiency in the security-based swap market and enable all market participants to have more comprehensive information with which to make trading and valuation determinations. Publicly disseminating these transactions also could reduce implicit transaction costs.[901] In addition, the amendments being adopted today reflect the Commission's assessment of the impact that the scope of security-based swap transactions subject to regulatory reporting may have on the ability of the Commission and other relevant authorities to detect emerging risks and abusive trading in the security-based swap market. Regulatory reporting of these transactions to a registered SDR should enhance the Commission's ability to oversee relevant activity related to security-based swap dealing occurring within the United States as well as to monitor market participants for compliance with specific Title VII requirements (including the requirement that a person register with the Commission as a security-based swap dealer if it exceeds the *de minimis* threshold).[902] The reporting of these transactions also will enhance the Commission's ability to monitor manipulative and abusive practices involving security-based swap transactions or transactions in related underlying assets, such as corporate bonds or other securities transactions that result from dealing activity, or other relevant activity, in the U.S. market.[903]

b. Transactions Executed on a Platform or By or Through a Registered Broker-Dealer

New Rule 908(a)(1)(iii) requires any security-based swap transaction that is executed on a platform having its principal place of business in the United States both to be reported to a registered SDR and to be publicly disseminated pursuant to Regulation SBSR. New Rule 908(a)(1)(iv) requires the reporting and public dissemination of any security-based swap transaction that is effected by or through a registered broker-dealer (including a registered SB SEF). The Commission notes that many security-based swaps that are executed on platforms or by or through a registered broker-dealer are already subject to Regulation SBSR because they meet one or both prongs of existing Rule 908(a)(1)—*i.e.,* there is a direct or indirect counterparty that is a U.S. person on either or both sides of the transaction or the security-based swap is accepted for clearing by a clearing agency having its principal place of business in the United States.[904] Thus, new Rules 908(a)(1)(iii) and (iv) extend regulatory reporting and public dissemination to an additional number of uncleared security-based swaps: Those involving only non-U.S. persons. The costs of reporting these additional cross-border security-based swaps are considered in the Commission's analysis of the amendments to Rule 901(a)(2)(ii)(E), which assigns the duty to report those cross-border security-based swaps.[905] Thus, new Rules 908(a)(1)(iii) and (iv) do not independently impose any additional reporting costs.

One commenter suggested that new Rule 908(a)(1)(iv) could provide incentives for non-U.S. counterparties to avoid transacting through registered broker-dealers, resulting in market fragmentation that would lead to adverse effects on risk management, market liquidity, and U.S. jobs.[906] The Commission acknowledges that market fragmentation could result if non-U.S. counterparties avoid transacting through registered broker-dealers. However, as discussed above, because of the small number of security-based swaps that are subject to Rule 908(a)(1)(iv), any market fragmentation due to the avoidance of registered broker-dealers by non-U.S. counterparties would be limited. To the extent that adverse effects on risk management, market liquidity, and U.S. jobs flow from market fragmentation, the Commission does not believe these effects should be significant, given the limited fragmentation that will likely arise as a result of the rule.

5. Amendments to Rule 908(b)

Rule 908(b) clarifies the types of persons that can incur duties under Regulation SBSR. In the Regulation SBSR Proposed Amendments Release, the Commission proposed to amend Rule 908(b) by adding platforms and registered clearing agencies to the list of persons that might incur obligations under Regulation SBSR.[907] The Commission has adopted these changes to Rule 908(b), as discussed in Section IX(F)(1), *supra.*

The Commission also is adopting new Rule 908(b)(5) to include a non-U.S. person that, in connection with such person's security-based swap dealing activity, arranged, negotiated, or executed a security-based swap using U.S. personnel. Because existing Rule 908(b)(2) covers a non-U.S. person that is registered as a security-based swap dealer, the effect of new Rule 908(b)(5) is to cover a foreign dealing entity that engages in ANE activity but that does not meet the *de minimis* threshold and thus would not have to register as a security-based swap dealer.

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that system to account for the different rules that apply to non-U.S. SBS depending on whether they are arranged, negotiated or executed by U.S. personnel. The non-U.S. SBSD would also need to train its front office personnel in the use of this new trade capture system and develop policies, procedures, and controls to require, track, and test the proper use of that system. In addition, the non-U.S. SBSD would need to seek and obtain waivers from non-U.S. counterparties—to the extent such waivers are even permitted—with respect to privacy, blocking and secrecy laws in local jurisdictions." *Id.* In the U.S. Activity Adopting Release, the Commission addressed generally the costs that firms would incur as a result of firms having to register as security-based swap dealers. *See* 81 FR at 8629–31.

[899] *See* IIB Letter at 16.

[900] *See supra* Section II(A)(6).

[901] *See* U.S. Activity Proposal, 80 FR at 27483–84.

[902] *See id.* at 27483.

[903] *See id.*

[904] *See* Rule 908(a)(2) (stating that a security-based swap that is not included within Rule 908(a)(1) shall be subject to regulatory reporting but not public dissemination if there is a direct or indirect counterparty on either or both sides of the transaction that is a registered security-based swap dealer or a registered major security-based swap participant).

[905] *See supra* Section XII(A)(1).

[906] *See* IIB Letter at 16–17.

[907] *See* 80 FR at 14759.

The costs incurred by an unregistered non-U.S. person that falls under Rule 908(b)(5) include the costs of setting up reporting infrastructure and compliance systems, which have been discussed in connection with the adoption of new Rules 901(a)(2)(ii)(E)(*2*) and (*3*).[908] Once an unregistered non-U.S. person's reporting infrastructure and compliance systems are in place, the marginal cost of reporting an individual transaction would be minimal [909] when compared to the costs of putting those systems in place and maintaining them over time.[910]

6. Other Conforming Amendments

As discussed in Section V(A), *supra*, the Commission today is adopting amendments to Rule 900(u) to expand the definition of ''participant'' to include platforms, registered clearing agencies that are required to report alpha dispositions pursuant to new Rule 901(e)(1)(ii), and registered broker-dealers that incur the duty to report security-based swap transactions pursuant to new Rule 901(a)(2)(ii)(E)(*4*).

Existing Rule 906(b) generally requires a participant of a registered SDR to provide the identity of its ultimate parent and any affiliates that also are participants of that registered SDR. In the Regulation SBSR Proposed Amendments Release, the Commission proposed to amend Rule 906(b) to except platforms and registered clearing agencies from this requirement. In the U.S. Activity Proposal, the Commission further proposed to amend Rule 906(b) to except from this requirement a registered broker-dealer that becomes a participant solely as a result of making a report to satisfy an obligation under Rule 901(a)(2)(ii)(E)(*4*). The Commission also proposed similar amendments to existing Rule 907(a)(6), which requires a registered SDR to have policies and procedures for periodically obtaining from each participant information that identifies the participant's ultimate parent(s) and any participant(s) with which the participant is affiliated, to avoid extending these policies and procedures to cover platforms, registered clearing agencies, and registered broker-dealers (assuming that they are not counterparties to security-based swap transactions). For the reasons discussed above,[911] the Commission is adopting these amendments. Accordingly, platforms, registered clearing agencies, and registered broker-dealers (assuming they are not counterparties to security-based swap transactions) will not incur costs to report ultimate parent and affiliate information and, registered SDRs will not incur costs to extend the scope of their policies and procedures.

Existing Rule 906(c) requires certain participants of a registered SDR to establish, maintain, and enforce written policies and procedures that are reasonably designed to ensure that the participant complies with any obligations to report information to a registered SDR in a manner consistent with Regulation SBSR. Rule 906(c) also requires participants covered by the rule to review and update their policies and procedures at least annually. In the Regulation SBSR Proposed Amendments Release, the Commission proposed to amend Rule 906(c) by extending this requirement to platforms and registered clearing agencies. In the U.S. Activity Proposal, the Commission proposed to amend Rule 906(c) by extending this requirement to a registered broker-dealer that incurs reporting obligations solely because it effects transactions between two unregistered non-U.S. persons that do not fall within proposed Rule 908(b)(5). In this release, the Commission is adopting the amendments to Rule 906(c) as proposed.

The Commission continues to estimate that the cost associated with establishing such policies and procedures, for each covered participant, will be approximately $58,000 and the cost associated with annual updates will be approximately $34,000.[912] Accordingly, the Commission estimates that the initial aggregate annual cost associated with the amendments to Rule 906(c) will be approximately $3,128,000, which corresponds to $92,000 per covered participant.[913] The Commission further estimates that the ongoing aggregate annual cost associated with the amendment Rule 906(c) will be approximately $1,156,000,[914] which corresponds to $34,000 per covered participant. The Commission believes that the costs imposed on participants by these amendments are necessary because written policies and procedures that are reasonably designed to ensure that covered participants comply with any obligations to report information to a registered SDR in a manner consistent with Regulation SBSR will enhance the overall reliability of security-based swap transaction data reported to registered SDRs.

Finally, existing Rule 901(d)(9) requires the reporting, if applicable, of the platform ID for a platform on which a security-based swap was executed. In the U.S. Activity Proposal, the Commission proposed to amend Rule 901(d)(9) to require the reporting, if applicable, of the broker ID of a registered broker-dealer (including a registered SB SEF) that is required by Rule 901(a)(2)(ii)(E)(*4*) to report a security-based swap effected by or through the registered broker-dealer.[915] As discussed above, the Commission has adopted the requirements that the registered broker-dealer effecting the transaction report the transaction.

As discussed in Section XII(A)(1)(d), *supra*, the Commission estimates that a maximum of 20 registered broker-dealers, excluding registered SB SEFs, will incur a reporting duty and together will report 540 security-based swaps per year. These 20 registered broker-dealers are subject to the amendment to Rule 901(d)(9) adopted herein. To comply with the amendment, a registered broker-dealer likely will build and maintain its reporting infrastructure to include the functionality to capture and incorporate its broker ID into transaction reports. The Commission believes that the cost of creating this functionality is part of the start-up cost of building the broker-dealer's reporting infrastructure,[916] while the cost of maintaining this functionality is part of the annual ongoing cost of the broker-dealer's reporting infrastructure.[917]

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[908] *See supra* Section XII(A)(1)(d).

[909] *See infra* Section XII(B)(1) (discussing the costs incurred by unregistered non-U.S. persons to assess whether they engage in ANE transactions and thus could incur reporting duties under Rule 901(a)(2)(ii)(E)).

[910] *See* Regulation SBSR Adopting Release, 80 FR at 14702.

[911] *See supra* Sections V (excepting platforms and registered clearing agencies from Rule 906(b)) and IX (excepting registered broker-dealers from Rule 906(b) if they become participants solely as a result of making a report to satisfy an obligation under Rule 901(a)(2)(ii)(E)(*4*)).

[912] *See* Regulation SBSR Adopting Release, 80 FR at 14716.

[913] The Commission derived its estimate from the following: [($58,000 + $34,000) × 34 covered participants (10 platforms + 4 registered clearing agencies + 20 registered broker-dealers)] = $3,128,000, or approximately $92,000 per covered participant.

[914] The Commission derived its estimate from the following: [$34,000 × 34 covered participants (10 platforms + 4 registered clearing agencies + 20 registered broker-dealers)] = $1,156,000, or approximately $34,000 per covered participant.

[915] As described above, final Rule 901(a)(2)(ii)(E)(*4*) requires a registered broker-dealer to report the information in Rules 901(c) and 901(d) for any transaction between two unregistered non-U.S. persons that do not fall within Rule 908(b)(5) where the transaction is effected by or through the registered broker-dealer.

[916] *See supra* Section XII(A)(1)(d), where the Commission estimates the total start-up cost to be $521,500 per registered broker-dealer and $10,430,000 in aggregate, across all registered broker-dealers.

7. Discussion of Comments Received

The Commission received a number of comments relating to its analysis of the programmatic costs and benefits associated with the amendments described above.

One commenter stated that the Commission lacks complete data to estimate the number of non-U.S. persons that engage in ANE transactions or the number of registered broker-dealers that intermediate security-based swap transactions, and recommended that the Commission collect a more complete set of data to more precisely estimate the number of non-U.S. persons that would be affected by the proposed rules. The commenter further argued that the lack of complete data made it difficult for the Commission to estimate the market impact, costs, and benefits associated with amendments that apply Regulation SBSR to ANE transactions and transactions intermediated by registered broker-dealers.[918]

The Commission acknowledges that there are limitations in the TIW data but believes that the data do allow the Commission to arrive at a reasonable estimate of the number of non-U.S. persons affected by the newly adopted rules. In Section II(A)(4)(d), *supra*, the Commission notes that it identified four foreign dealing entities that likely engaged in ANE activity in 2015 but, based on the level of relevant activity, would be unlikely to register as security-based swap dealers. Based on the analysis, the Commission estimates that four unregistered foreign dealing entities will engage in ANE activity and thus be affected by the newly adopted rules.[919] In Section XII(A)(1)(d), *supra*, the Commission estimates the compliance costs associated with Rule 901 for these four unregistered foreign dealing entities.[920] As discussed earlier, these programmatic costs are part of the programmatic costs associated with Rule 901 that were accounted for in the Regulation SBSR Adopting Release. While data limitations do not allow the quantification of the benefits associated with the amendments that apply Regulation SBSR to ANE transactions and transactions intermediated by registered broker-dealers, the Commission discusses these benefits qualitatively in Section XIII(H), *infra*.

B. Assessment Costs of Unregistered Entities Related to ANE Transactions

1. Assessment Costs of Foreign Dealing Entities Engaging in ANE Transactions

New Rule 908(b)(5) provides that an unregistered foreign dealing entity that engages in ANE transactions may incur reporting duties under Regulation SBSR, and the amendments to Rule 901(a)(2)(ii)(E) adopted herein provide that such foreign dealing entities will be the reporting side in certain cases. Thus, unregistered foreign dealing entities will incur costs to assess whether they engage in ANE transactions and, if so, whether they will incur reporting duties under Rule 901(a)(2)(ii)(E). The Commission estimates that four unregistered foreign dealing entities will incur such assessment costs. The four unregistered foreign dealing entities are in addition to the 20 additional non-U.S. persons that the Commission estimated would incur assessment costs as a result of the rules finalized in the U.S. Activity Adopting Release.[921] In what follows, the Commission discusses costs that these four unregistered foreign dealing entities might incur to assess whether they engage in ANE transactions.

In the U.S. Activity Adopting Release, the Commission discussed the approaches that market participants may use to determine which transactions involve relevant activity involving U.S. personnel and thus would apply toward dealer *de minimis* thresholds. The Commission notes that, as an initial matter, a foreign dealing entity likely will review its current dealing operations to ascertain whether it has U.S. personnel that could be used to arrange, negotiate, or execute security-based swaps. The Commission believes that such a determination will not result in significant costs because it requires only that the foreign dealing entity check for the existence of U.S. personnel. If the foreign dealing entity does not have U.S. personnel that could be used to arrange, negotiate, or execute security-based swaps, then the foreign dealing entity's assessment of whether it has engaged in ANE activity ends.

If, based on the review described above, the foreign dealing entity determines that it has U.S. personnel that could be used to arrange, negotiate, or execute security-based swaps, then the foreign dealing entity could choose between a number of alternative means of compliance.[922] One alternative would be for the entity to implement systems to check the location of personnel used in arranging, negotiating, or executing individual security-based swap transactions. The Commission believes that the cost of developing and modifying systems to track the location of persons with dealing activity will be substantially similar to the costs of such systems discussed in the U.S. Activity Adopting Release, or $410,000 for the average foreign dealing entity. To the extent that non-U.S. persons already employ systems that track the location of persons with dealing activity, the costs of modifying such IT systems may be lower than the Commission's estimate.[923] In addition to the development or modification of such systems, the Commission estimates that entities would incur the cost of $6,500 per location per year on an ongoing basis for training, compliance, and verification costs.[924] Second, the foreign dealing entity could choose to restrict personnel located in a U.S. branch or office from engaging in ANE activity in connection with the entity's dealing activity with non-U.S. counterparties. Such a restriction on communication and staffing for purposes of avoiding certain Title VII requirements would reduce the costs of assessing the location of personnel involved in ANE activity and could remove entirely the need to implement systems to track the activities of U.S. personnel on a per-transaction basis. The Commission estimates that the costs of establishing policies and procedures to restrict communication between personnel located in the United States employed by non-U.S. persons (or their agents) and other personnel involved in dealing activity would be approximately $28,300 for each entity that chooses this approach.[925]

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[917] *See supra* Section XII(A)(1)(d), where the Commission estimates the ongoing cost per year to be $316,500 per registered broker-dealer, and $6,330,000 for all registered broker-dealers.

[918] *See* ISDA I at 3, 7. This commenter also argued that the data available to the Commission at the time of the proposal would not have allowed the Commission to precisely estimate, among other things, the number of non-U.S. persons that carry out dealing activity using personnel in the United States. *See id.* at 7.

[919] Because of the relatively low volume of transaction activity of these four entities during 2015 and the existence of affiliations with other entities expected to register as security-based swap dealers, the Commission believes, even after accounting for growth in the security-based swap market and acknowledging the limitations of the transaction data available for analysis, four is a reasonable estimate of the number of unregistered dealing entities likely to incur assessment costs as a result of new Rule 908(b)(5).

[920] The initial aggregate annual costs associated with Rule 901 will be approximately $3,668,000, which corresponds to approximately $524,000 per unregistered entity. The Commission estimates that the ongoing aggregate annual costs on an unregistered entity associated with Rule 901 will be approximately $2,233,000, which corresponds to approximately $319,000 per unregistered entity.

[921] *See* U.S. Activity Adopting Release, 81 FR at 8627. This is calculated as 134 non-U.S. persons likely to incur assessment costs to determine the level of ANE activity, less the 114 persons that are likely to incur assessment costs associated with the dealer *de minimis* rules adopted in the Cross-Border Adopting Release.

[922] *See* U.S. Activity Adopting Release, 81 FR at 8627–28.

[923] *See id.* at 8627.

[924] This cost is calculated as (internal cost, 90 hours × $50 per hour = $4,500) + (consulting costs, 10 hours × $200 per hour = $2,000) = a total cost of $6,500 per location per year. *See also* U.S. Activity Adopting Release, 81 FR at 8627.

Finally, a foreign dealing entity could avoid assessing transactions on a per-transaction basis by choosing to report all transactions to a registered SDR, regardless of the location of personnel engaged in ANE activity. Such an alternative may be reasonable for foreign dealing entities that expect few transactions involving foreign counterparties to be arranged, negotiated, or executed by personnel located outside the United States, such as foreign dealing entities that primarily transact in security-based swaps on U.S. reference entities or securities, and generally rely on personnel located in the United States to perform market-facing activities.[926]

The Commission believes that the same principles apply to foreign dealing entities that rely on agents to arrange, negotiate, or execute security-based swaps on their behalf. The Commission anticipates that foreign dealing entities may employ any of the strategies above to comply with the final rules through the choice of their agents. For example, a foreign dealing entity may choose an agent that does not use U.S.-based personnel for arranging, negotiating, or executing security-based swap transactions with non-U.S. counterparties to avoid assessment costs. The Commission also anticipates that a foreign dealing entity might rely on representations from its agents about whether transactions conducted on its behalf involved relevant dealing activity by personnel from a location in the United States. This could occur on a transaction-by-transaction basis, or, if the agent uses personnel located in the United States in all or none of its transactions, it could choose to make a representation about the entirety of the agent's business.

As in the U.S. Activity Adopting Release, the Commission believes that a foreign dealing entity will inform its choice between the alternative compliance strategies with a one-time review of its security-based swap business lines. This review likely will encompass both employees of the foreign dealing entity as well as employees of agents used by the foreign dealing entity, and identify whether these personnel are involved in arranging, negotiating, or executing security-based swaps. The information gathered as a result of this review will allow the foreign dealing entity to assess the revenues that it expects to flow from transaction activity performed by U.S. personnel. This information also will help these market participants form preliminary estimates about the costs associated with various alternative compliance strategies, including the trade-by-trade analysis outlined above. This initial review may be followed with reassessment at regular intervals or subsequent to major changes in the market participant's security-based swap business, such as acquisition or divestiture of business units. The Commission estimates that the per-entity initial costs of a review of business lines will be approximately $104,000. Further, the Commission believes that periodic reassessment of business lines will cost, on average, $52,000 per year, per entity.[927]

2. Assessment Costs of Unregistered U.S. Persons Engaging in Security-Based Swaps Against Foreign Entities

New Rules 901(a)(2)(ii)(E)(*2*) and 901(*3*) create reporting duties for unregistered U.S. persons that transact security-based swaps with unregistered entities. Under Rule 901(a)(2)(ii)(E)(*2*), in a transaction between an unregistered U.S. person and an unregistered foreign dealing entity that is engaging in ANE activity, the sides would be required to select the reporting side. Under Rule 901(a)(2)(ii)(E)(*3*), in a transaction between an unregistered U.S. person and an unregistered non-U.S. person that is not engaging in ANE activity, the unregistered U.S. person is the reporting side. Because of these reporting duties, an unregistered U.S. person could incur costs to assess whether its foreign counterparty in a security-based swap transaction is an unregistered foreign dealing entity engaging in ANE activity.

The Commission believes that unregistered U.S. persons likely will seek to avoid the costs of assessing whether a foreign counterparty is engaging in ANE activity by choosing to transact only with registered entities for which assessment is not required.[928] The incentive of unregistered U.S. persons to avoid transacting with unregistered foreign counterparties is strengthened by the fact that there will be very few unregistered foreign dealing entities that might engage in ANE activities, and that they likely will participate in a relatively small number of security-based swap transactions in the U.S. market. As noted earlier,[929] the Commission estimates that only four foreign dealing entities will remain below the *de minimis* threshold and thus not have to register as security-based swap dealers.[930] Furthermore, to the extent that the usage of U.S. personnel by such a foreign dealing entity to engage in ANE activity is a question for a unregistered U.S. person who is a potential counterparty, the foreign dealing entity has an incentive to readily provide this information to the unregistered U.S. person—thereby obviating the need for the U.S. person to conduct an assessment—and to agree to be the reporting side. If the foreign dealing entity did not agree to be the reporting side, the unregistered U.S. person would have the option of transacting with one of several registered security-based swap dealers, both U.S. and foreign, for which the U.S. counterparty would not have to assess for ANE activity or negotiate with the other side about the reporting duty, because the duty would fall to the registered security-based swap dealer pursuant to existing Rule 901(a)(2)(ii)(B). Therefore, the Commission believes that any assessment costs incurred by unregistered U.S. persons will be limited.

3. Assessment Costs Associated With Rule 901(a)(2)(ii)(E)(*4*)

Under new Rule 901(a)(2)(ii)(E)(*4*), respondent broker-dealers (including SB SEFs) will be required to report security-based swap transactions that they intermediate if neither side incurs the duty to report (*i.e.*, neither side includes a U.S. person, a registered security-based swap dealer, a registered major security-based swap participant, or a non-U.S. person engaging in an ANE transaction). As a result, respondent broker-dealers will incur certain costs to assess the circumstances in which they incur the duty to report transactions because neither side incurs the duty. Any such assessment costs are reflected in the cost estimates for the policies and procedures that respondent broker-dealers are required to establish, maintain, and enforce under Rule

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[925] *See id.* at 8628.

[926] *See id.*

[927] *See id.* at n. 283.

[928] *See infra* Section XIII(H)(1) (discussing the potential competitive effects associated with assessments for ANE activity by unregistered U.S. persons).

[929] *See supra* note 885 and accompanying text.

[930] For foreign dealing entities that register with the Commission as security-based swap dealers, reporting duties stem from their registration status, not from the presence of any ANE activity. Therefore, for these entities, no assessment will be needed to know whether a reporting duty arises from a particular transaction.

906(c).[931] The programmatic costs estimated by the Commission for the amendment to Rule 906(c) already incorporate the cost incurred by respondent broker-dealers when assessing whether they have a duty to report security-based swap transactions. Therefore, respondent broker-dealers will not incur any additional costs beyond the programmatic cost for the amendment to Rule 906(c) adopted herein.[932]

4. Discussion of Comments Received

The Commission received a number of comments relating to its analysis of the assessment costs associated with the proposed amendments to Rules 901 and 908 included in the U.S. Activity Proposal. One commenter pointed out that the Commission's analysis of assessment costs was incomplete because the analysis did not account for the additional work that market participants might undertake to meet reporting requirements during the Interim Period (*i.e.*, the period beginning on Compliance Date 1 but before the SBS entities registration compliance date).[933] According to the commenter, this additional work and the associated cost could be avoided if the Commission scheduled Compliance Date 1 after the SBS entities registration compliance date.[934] The same commenter also suggested that the Commission's cost analysis failed to account for the possibility that some of the documentation and processes developed by market participants for Interim Period reporting would become obsolete after security-based swap dealers register with the Commission.[935]

As discussed in Section X(C), *supra*, the Commission acknowledges the commenters' concerns that requiring compliance with Regulation SBSR before the SBS entities registration compliance date would have raised numerous challenges, and that addressing these challenges would have necessitated time and investment to create interim solutions that might not have been useful after the SBS entities registration compliance date. Therefore, the Commission has determined that market participants will not be required to comply with Regulation SBSR until after the SBS entities registration compliance date.

XIII. Economic Effects and Effects on Efficiency, Competition, and Capital Formation

Section 3(f) of the Exchange Act[936] requires the Commission, whenever it engages in rulemaking and is required to consider or determine whether an action is necessary or appropriate in the public interest, to consider, in addition to the protection of investors, whether the action will promote efficiency, competition, and capital formation. In addition, Section 23(a)(2) of the Exchange Act[937] requires the Commission, when making rules under the Exchange Act, to consider the impact of such rules on competition. Section 23(a)(2) also prohibits the Commission from adopting any rule that would impose a burden on competition not necessary or appropriate in furtherance of the purposes of the Exchange Act.

The Commission believes that the amendments to Regulation SBSR adopted herein will result in further progress towards providing a means for the Commission and other relevant authorities to gain a better understanding of the aggregate risk exposures and trading behaviors of participants in the security-based swap market; facilitate public dissemination of security-based swap transaction information, thus promoting price discovery and competition by improving the level of information to all market participants; and improve risk management by security-based swap counterparties.[938]

The economic effects of these amendments on firms that provide infrastructure services to security-based swap counterparties and the security-based swap market generally are discussed in detail below. The Commission also considered the effects that these amendments might have on efficiency, competition, and capital formation. The Commission believes that its action today is likely to affect competition among firms that provide security-based swap infrastructure services to market participants and affect efficiency as a result of the way that these amendments allocate regulatory burdens. The effects of these amendments on capital formation are likely to be indirect and will result from the way in which these amendments affect the behavior of registered clearing agencies, counterparties to security-based swaps, and registered SDRs. To the extent that these amendments promote more efficient provision of security-based swap market infrastructure services, there would be lower transactions costs,[939] which would free resources for investment and capital formation.

This analysis has been informed by the relationships among regulation, competition, and market power discussed in Section II(B), *supra*. An environment in which there is limited competition in SDR services could impose costs on the security-based swap market, including higher prices or lower quality services from SDRs. For example, a registered SDR that faces few or no competitors could seek to impose higher prices, because persons with a duty to report security-based swaps under Regulation SBSR might not be able to identify a competing SDR that offers prices close enough to marginal cost to make changing service providers efficient. Further, if consumers of SDR services have few alternative suppliers from which to choose, SDRs would have fewer incentives to produce more efficient SDR processes and services. This combination of higher prices for SDR services and/or less efficient SDR services could reduce security-based swap transaction activity undertaken by market participants to hedge assets that have cash flows that are related to the cash flows of security-based swaps. A reduction in hedging activity through security-based swaps could reduce the values of assets held by market participants and in turn result in welfare losses for these market participants.

However, there could be some offsetting benefit to limited competition in the market for SDR services for both regulatory authorities and the public. A small set of registered SDRs could make it simpler for the Commission and other relevant authorities to build a complete picture of transaction activity and outstanding risk exposures in the security-based swap market, and could limit the need for market observers to aggregate the security-based swap transaction data disseminated by multiple SDRs before using it as an input to economic decisions.

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[931] *See supra* Section XII(A)(3) (discussing the costs of amended Rule 906(c)).

[932] *See id.*

[933] *See* ISDA II at 11 (stating that the additional work involves efforts to "exchange transaction level party data, develop a new approach to use the tie-breaker logic, enter into reporting side agreements and delegation agreements, and build dual sets of reporting side logic to develop an organized industry approach to comply with SBSR"); ISDA III at 9 (stating that the Commission did not consider the cost and effort that market participants would spend to develop and implement interim reporting side agreements, and the "cost that market infrastructure providers would incur to duplicate efforts in order to support both pre- and post-registration reporting side approaches").

[934] *See* ISDA II at 12; ISDA III at 9, 12.

[935] *See* ISDA I at 13.

[936] 15 U.S.C. 78c(f).

[937] 15 U.S.C. 78w(a)(2).

[938] *See* 80 FR at 14779.

[939] These transactions costs would include both implicit and explicit costs. Implicit transactions costs are the spread between transaction prices and the fundamental value of the assets being traded. Explicit transactions costs, by contrast, are commissions and other fees paid by counterparties for effecting transactions in the market.

The Commission also considered the effects on efficiency, competition, and capital formation stemming from the amendments to Rules 901 and 908 that will subject additional cross-border security-based swaps to regulatory reporting and public dissemination, and assign the duty to report those cross-border transactions. The adopted amendments might affect the security-based swap market in a number of ways, many of which are difficult to quantify. In particular, a number of the potential effects that the Commission discusses below are related to price efficiency, liquidity, and risk sharing. These effects are difficult to quantity for a number of reasons. First, in many cases the effects are contingent upon strategic responses of market participants. For instance, the Commission notes in Section XIII(H)(2), *infra,* that under the adopted approach non-U.S. persons may choose to relocate personnel, making it difficult for U.S. counterparties to access liquidity in security-based swaps. The magnitude of these effects on liquidity and on risk sharing depend upon a number of factors that the Commission cannot estimate, including the likelihood of relocation, the availability of substitute liquidity suppliers, and the availability of substitute hedging assets. Therefore, much of the discussion below is qualitative in nature, although the Commission tries to describe, where possible, the direction of these effects.

Not only can some of these effects be difficult to quantify, but there are many cases where a rule could have two opposing effects, making it difficult to estimate a net impact on efficiency, competition, or capital formation. For example, in the discussion of the net effect of certain amendments to Regulation SBSR on efficiency, the Commission expects that post-trade transparency may have a positive effect on price efficiency, while it could negatively affect liquidity by providing incentives for non-U.S. persons to avoid contact with U.S. persons. The magnitude of these two opposing effects will depend on factors such as the sensitivity of traders to information about order flow, the impact of public dissemination of transaction information on the execution costs of large orders, and the ease with which non-U.S. persons can find substitutes that avoid contact with U.S. personnel. Each of these factors is difficult to quantify individually, which makes the net impact on efficiency equally difficult to quantify.

A. Reporting of Clearing Transactions

New Rule 901(a)(2)(i) assigns the duty to report a security-based swap that has a registered clearing agency as a direct counterparty to that registered clearing agency. Existing Rule 901(a) does not assign reporting obligations for any clearing transactions; thus, in the absence of Rule 901(a)(2)(i), clearing transactions would not be subject to any regulatory reporting requirement. Without a requirement for clearing transactions to be reported to a registered SDR, the Commission and other relevant authorities would have only limited ability to carry out market oversight functions. For example, while the Commission could access transaction reports of alphas and uncleared transactions, the Commission would not be able to obtain from registered SDRs information about the open security-based swap positions of the relevant counterparties after alpha transactions are cleared. Requiring that clearing transactions be reported to registered SDRs and delineating reporting responsibilities for these transactions are particularly important given the level of voluntary clearing activity in the market as well as the mandatory clearing determinations that will be required under Title VII.[940]

The Commission believes that, because a registered clearing agency creates the clearing transactions to which it is a counterparty, the registered clearing agency is in the best position to provide complete and accurate information for the clearing transactions resulting from the security-based swaps that it clears.[941] If the Commission assigned the reporting obligation for clearing transactions to a person who lacked direct access to the information required to be reported, that person would be obligated to obtain the required information from the clearing agency or another party who had access to the information to discharge its reporting obligation. Thus, assigning reporting obligations to the non-clearing-agency side could increase the number of reporting steps, thereby increasing the possibility of discrepancy, error, or delay in the reporting process. Placing the reporting duty on the non-clearing-agency side could also reduce data reliability if the data has to be reconfigured to be acceptable by the SDR.[942] Inaccurate or delayed reporting of clearing transactions would negatively impact the ability of the Commission and other relevant authorities to understand, aggregate, and act on the transaction information.

New Rule 901(a)(2)(i) also allows the registered clearing agency that is required to report all clearing transactions to which it is a counterparty to select the registered SDR to which to report. As noted in Section II(B), *supra,* because many of the infrastructure requirements for entrant SDRs are shared by registered clearing agencies, registered clearing agencies might pursue vertical integration into the market for SDR services at a lower cost relative to potential entrants from unrelated markets. If the costs of reporting to affiliated SDRs are lower than the costs of reporting to unaffiliated SDRs, registered clearing agencies will likely choose to report clearing transactions to an affiliated SDR. Because a registered clearing agency is likely to be involved in developing an affiliated SDR's systems, the clearing agency will likely avoid costs related to translating or reformatting data due to incompatibilities between data reporting by the registered clearing agency and data intake by the SDR. To the extent that a clearing agency incurs a lower cost when connecting to an affiliated SDR, the cost of reporting clearing transactions to an affiliated SDR is likely to be lower than the cost of reporting to an independent SDR. While both a clearing-agency-affiliated SDR and an independent SDR could lower their average costs by adding clearing transactions to their existing volume of reported transactions, only the clearing agency can reduce the cost of connecting to its affiliated SDR.

Vertical integration of security-based swap clearing and SDR services could be beneficial to other market participants if they ultimately share in these efficiency gains. For example, efficiency gains due to straight-through processing from execution to reporting could lower transactions costs for market participants and reduce the likelihood of data discrepancies and delays. Even if registered clearing agencies do not enter the market for SDR services, the potential for them to pursue a vertical integration strategy could motivate independent SDRs to offer more competitive service models.

The Commission is aware of the potential costs of allowing registered clearing agencies to select the SDR to which they report. If Rule 901(a)(2)(i) encourages the formation of clearing-agency-affiliated SDRs that would not otherwise emerge, the aggregate number of registered SDRs might reflect an inefficient level of service provision. Once an entity has established the functionality to offer clearing and central counterparty services for security-based swaps, only marginal additional investments would likely be needed to offer SDR services. The ease with which registered clearing agencies set up affiliated SDRs could affect how well all SDRs exploit economies of scale. As noted in Section II(B)(2), *supra*, in the market for SDR services, economies of scale arise from the ability to amortize the fixed costs associated with infrastructure over a large volume of transactions. With a fixed volume of reportable transactions, exploitation of economies of scale by each SDR becomes more limited as the number of SDRs increases. Thus, the entry of clearing-agency-affiliated SDRs could indicate that each SDR benefits from an affiliation with a clearing agency and might not, in aggregate, result in the provision of transaction reporting services at a lower per-transaction cost than if there were fewer SDRs. Inefficiencies could result if the Commission and the public had to receive and process security-based swap transaction data from a larger number of registered SDRs. Connecting to a larger number of SDRs and merging transaction data with potentially different data formats could be costly and difficult.

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[940] *See* General Policy on Sequencing, 77 FR at 35636.

[941] Although registered clearing agencies might pass on the costs associated with reporting clearing transactions, at least in part, to their non-reporting counterparties, the costs that are passed on to non-reporting parties are likely to be lower than the costs that the non-reporting parties would face if they had direct responsibility to report these transactions.

[942] *See supra* Section III(B).

The potential for efficiency gains through vertical integration of clearing agencies and SDRs could foreclose entry into the market for SDR services except by firms that are already present in the market for clearing agency services. Registered clearing agencies are more likely to benefit from efficiencies in shared infrastructure than independent SDRs, given that it is more difficult for an SDR to enter the market for clearing services than for a clearing agency to enter the market for SDR services.[943] Moreover, to the extent that an affiliated SDR is not as cost-effective as a competing independent SDR, a registered clearing agency could subsidize the operation of its affiliate SDR to provide a competitive advantage in its cost structure over independent SDRs. Hence, providing a registered clearing agency with the discretion to select the registered SDR could provide a competitive advantage for clearing-agency-affiliated SDRs relative to independent SDRs. If a registered clearing agency subsidizes its affiliated SDR using revenue generated from its clearing business, the clearing agency's members would indirectly bear some of the costs of operating the affiliated SDR. Such an allocation of SDR cost to clearing members could be inefficient because the benefits of reporting transactions to an SDR (*i.e.*, the benefits of regulatory reporting and public dissemination) accrue to market participants generally, and not just to clearing members.

As a result of new Rule 901(a)(2)(i), clearing members might find that the records of their security-based swap transactions are fragmented across multiple registered SDRs (*i.e.*, alpha SDRs and, in addition, clearing-agency-affiliated SDRs to which registered clearing agencies report clearing transactions). The Commission does not believe, however, that fragmentation in the storage of transaction reports would create significant difficulties or inefficiencies for a clearing member that wishes to consolidate all its security-based swap transaction reports at a chosen SDR to facilitate activities such as risk management. Such a clearing member might contract with a registered clearing agency, for a fee, to transmit data for its clearing transactions to an SDR of the clearing member's choice as a duplicate report. This would allow the registered clearing agency to satisfy its obligations while permitting the clearing member to establish and maintain access to a consolidated record of all of its security-based swap transactions in a single SDR. However, in this case, the registered clearing agency could choose a fee schedule that encourages the clearing member to report its uncleared bilateral transactions to the affiliated SDR. Such a fee schedule might involve the clearing agency offering to terminate alpha transactions reported to its affiliate SDR for a lower price than alpha transactions to an independent SDR.

As discussed in Section XII(B)(1)(a), *supra*, the Commission has estimated the annual and on-going costs associated with requiring registered clearing agencies to establish connections to registered SDRs. The Commission believes that, for a given registered clearing agency, these costs are likely to be lower for a connection to an affiliated SDR than to an independent SDR. Because the registered clearing agency is likely to have been involved in developing its affiliated SDR's systems, the clearing agency can likely avoid costs related to translating or reformatting data due to incompatibilities between the clearing agency's data format and the data format required by the SDR. The reporting of clearing transactions by registered clearing agencies to their affiliated SDRs could promote efficiency in two ways. First, a registered clearing agency would incur lower connection costs when reporting to an affiliated SDR. Second, the quality of transaction data available to the Commission could be improved to the extent that the Commission gains access to marginally more reliable transaction data because reporting by a registered clearing agency to an affiliated SDR avoids introducing errors or other data discrepancies that otherwise could occur when translating or reformatting transaction data for submission to an independent SDR.

B. Alternative Approaches to Reporting Clearing Transactions

As part of the economic analysis of the amendments adopted herein, the Commission has considered the market power that providers of security-based swap market infrastructure might be able to exercise in pricing the services that they offer and the possibility that these infrastructures could shift the costs created by regulatory burdens onto their customers. The Commission included these economic considerations in its evaluation of alternative approaches to assigning reporting obligations for clearing transactions. As outlined above, the Commission considered four alternatives for assigning these reporting obligations as well as comments received related to these alternatives. The following section discusses the likely economic effects of these alternatives, including their likely impacts on efficiency, competition, and, indirectly, capital formation.

1. Alternative 1

The first alternative would be to apply the reporting hierarchy in existing Rule 901(a)(2)(ii) to clearing transactions. Under Alternative 1, a counterparty to a clearing transaction other than the clearing agency, such as a registered security-based swap dealer, would have the duty to report the clearing transaction. As discussed above, assigning reporting obligations to the non-clearing-agency side could increase the number of reporting steps, thereby increasing the possibility of discrepancy, error, or delay in the reporting process. Placing the reporting duty on the non-clearing-agency side also could reduce data reliability if the data has to be reconfigured to be acceptable by the SDR.[944]

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[943] A registered clearing agency, particularly one that acts as a central counterparty for security-based swaps, needs significant financial resources to ensure that it can absorb losses from clearing member defaults, while SDRs do not. Similarly, a registered clearing agency requires significant risk management expertise that an SDR does not. Thus, the barriers to entry into the clearing agency market are higher than the barriers to entry into the SDR market.

The Commission continues to believe that it is unlikely that non-clearing-agency counterparties would be subject to significant additional costs associated with building infrastructure to support regulatory reporting for clearing transactions under this alternative, for two reasons.[945] First, to the extent that market participants that submit security-based swaps to clearing also engage in uncleared transactions and sit atop the reporting hierarchy, they likely already have the required infrastructure in place to support regulatory reporting of alphas and uncleared transactions. The Commission anticipates that, as a result, there might be only marginal additional costs for reporting sides to report clearing transactions, if the Commission selected Alternative 1. Moreover, the Commission anticipates that, once infrastructure is built, the per-transaction cost of data transmission would not vary substantially between registered clearing agencies, who are required to report under new Rule 901(a)(2)(i), and reporting sides, who would be required to report under Alternative 1.

Second, non-clearing agency counterparties, particularly those who engage solely in cleared trades or who are not high in the reporting hierarchy, could enter into an agreement under which the registered clearing agency would submit the information to a registered SDR on their behalf. This service could be bundled as part of the other clearing services purchased, and would result in an outcome substantially similar to giving the registered clearing agency the duty to report. One difference, however, is that the customer of the registered clearing agency could, under this alternative, request that the information be submitted to a registered SDR unaffiliated with the registered clearing agency, a choice that, under the adopted approach, is at the discretion of the registered clearing agency. Nevertheless, the Commission believes that, to the extent that it is economically efficient for the registered clearing agency to report the details of cleared transactions on behalf of its counterparties, Alternative 1 would likely result in ongoing costs of data transmission for market participants and infrastructure providers that are, in the aggregate, similar to the Commission's approach in Rule 901(a)(2)(i).

If registered clearing agencies reporting to registered SDRs on behalf of counterparties is not available under Alternative 1, then some counterparties would be required to build infrastructure to support regulatory reporting for clearing transactions. Analysis of single-name CDS transactions in 2015 in which a clearing agency was a direct counterparty shows approximately 54 market participants that are not likely to register as security-based swap dealers or major security-based swap participants, and therefore might be required to build infrastructure to support regulatory reporting for clearing transactions in order to maintain current trading practices in the security-based swap market.[946] One commenter asserted that the Commission did not adequately address the role of third parties that could perform reporting duties on behalf of reporting parties.[947] As noted in Section III(B), *supra,* Regulation SBSR permits the use of agents to carry out reporting duties and the Commission expects that a market participant that would be assigned the reporting obligation for clearing transactions under Alternative 1 would contract with an agent if it expects use of an agent to be less costly than carrying out the reporting obligation itself. As a result, the ability to use agents could further reduce costs to market participants under Alternative 1.

Under Alternative 1, non-clearing-agency counterparties would have the ability to choose which registered SDR receives their reports. Because non-clearing-agency counterparties would have this choice, registered SDRs under the alternative approach might have additional incentive to provide high levels of service to attract this reporting business by, for example, providing such counterparties with convenient access to reports submitted to the registered SDR or by supporting the counterparties' efforts at data validation and error correction. Additionally, ensuring that these counterparties have discretion over which registered SDR receives the transaction data could allow these counterparties to consolidate their security-based swap transactions into a single SDR for record-keeping purposes or for operational reasons, though only to the extent that they can identify a registered SDR that accepts reports for all relevant asset classes.

In assessing Alternative 1, the Commission recognizes that registered clearing agencies have a comparative advantage in processing and preparing data for reporting cleared transactions to a registered SDR. Registered clearing agencies terminate alpha transactions, as well as create beta and gamma transactions and all subsequent netting transactions, and so already possess all of the relevant information to report these transaction events to a registered SDR. Moreover, the volume of transactions at registered clearing agencies means that they can amortize the fixed costs of establishing and maintaining connections to a registered SDR over a large quantity of reportable activity, potentially allowing them to report transactions at a lower average cost per transaction than many other market participants, particularly non-registered persons.

The Commission believes that, given this comparative advantage, applying to clearing transactions the same reporting hierarchy that it has adopted for uncleared transactions would result in a registered clearing agency reporting the transaction data to a registered SDR of a non-clearing-agency counterparty's choice as a service to the non-clearing-agency counterparties to its clearing transactions. In this respect, the entity that performs the actual reporting of clearing transactions would likely be the same as with adopted Rule 901(a)(2)(i), which would assign this duty to the registered clearing agency. The key difference under Alternative 1 is that the non-clearing-agency counterparty would generate this responsibility through private contract and could terminate the agreement and assume the reporting responsibility, should it perceive the fee or service terms as unreasonable. Such an agreement also could specify the registered SDR to which the clearing agency should send transaction data on behalf of the non-clearing-agency counterparty. The ability to terminate such an agreement could diminish the potential bargaining power that the registered clearing agency would otherwise have if the registered clearing agency were assigned the duty to report. Further, by allowing the non-clearing-agency counterparty to choose between registered SDRs, such an agreement could promote competition between SDRs.

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[944] *See supra* Section III(B).

[945] *See* Regulation SBSR Proposed Amendments Release, 80 FR at 14781.

[946] *See* Regulation SBSR Proposed Amendments Release, 80 FR at 14781–82. To arrive at this estimate, the Commission staff used single-name CDS transaction data for 2015 to produce a list of all direct counterparties to a clearing agency and removed those persons likely to register as security-based swap dealers or major security-based swap participants. The list of likely registrants was constructed using the methodology described in the Cross-Border Adopting Release. *See* 79 FR at 47296, n. 150 (describing the methodology employed by the Commission to estimate the number of potential security-based swap dealers); *id.* at 47297, n. 153 (describing the methodology employed by the Commission to estimate the number of potential major security-based swap participants).

[947] *See* Markit Letter at 8.

However, because the non-clearing-agency counterparty might still have to rely on assistance from the clearing agency to satisfy the reporting obligations—particularly for any subsequent clearing transactions resulting from netting and compression of multiple betas and gammas—the reduction in clearing agency bargaining power might not be substantial. A registered clearing agency that supplies this information and converts it into the format prescribed by a non-clearing-agency counterparty's chosen SDR so that the counterparty can fulfill its reporting duty by submitting transaction data to a registered SDR of its choice could still have significant bargaining power with respect to providing that information.

The Commission believes that the adopted rules are generally consistent with the outcome under Alternative 1 in a number of key respects. First, under both approaches to reporting—one in which the Commission assigns the reporting responsibility for clearing transactions to registered clearing agencies, and the other in which the market allocates the reporting responsibility in the same way—it is likely that registered clearing agencies will report clearing transactions to their affiliated SDRs.[948] Under an approach in which the Commission does not assign any reporting duties to registered clearing agencies, counterparties would likely be assessed an explicit fee by registered clearing agencies for submitting reports on the counterparties' behalf. Under Rule 901(a)(2)(i), the fees associated with these services will likely be part of the total fees associated with clearing security-based swaps.

In light of comments received on its proposal, the Commission acknowledges caveats to this analysis.[949] Under Alternative 1, a non-clearing agency counterparty may alter the disposition of its clearing transaction data as a result of having the right to select the registered SDR to which this information is submitted. In particular, a non-clearing agency counterparty with the duty to report clearing transactions would compare the costs and benefits of contracting with the clearing agency to fulfil reporting obligations on its behalf by reporting to an affiliated SDR,[950] with the costs and benefits of alternative arrangements that would place the same data at an independent SDR of its choice.

Second, under Alternative 1 and under the adopted approach, efficiency gains stemming from consolidation of the reporting function within registered clearing agencies would be split between such clearing agencies and security-based swap counterparties. The difference between these two regulatory approaches turn on how these gains are split.

The Commission believes that Alternative 1 would not necessarily restrict the ability of registered clearing agencies to exercise market power in ways that may allow them to capture the bulk of any efficiency gains.[951] First, while a counterparty to a registered clearing agency could contract with the clearing agency to receive the information about netting and compression transactions that would enable re-transmission of the cleared transaction data to a registered SDR, depending on the policies and procedures of the registered clearing agency, these data might not be in the format that is required for submission to the counterparty's SDR of choice. As a result, counterparties to registered clearing agencies would bear the costs associated with restructuring the data that they receive from registered clearing agencies before submitting transaction reports to a registered SDR. Such costs could limit the feasibility of assuming the reporting responsibility rather than contracting to have the registered clearing agency perform the duty. However, the Commission acknowledges, in line with comments received on its proposal,[952] that the use of agents to carry out reporting duties could mitigate these costs, if agents are able to restructure data more efficiently than counterparties.

Second, in an environment where reporting obligations for clearing transactions rest with counterparties and there is limited competition among registered clearing agencies, registered clearing agencies might be able to charge high fees to counterparties who must rely on them to provide information necessary to make required reports to registered SDRs. A registered clearing agency could otherwise impair the ability of its counterparties to perform their own reporting if the clearing agency does not provide sufficient support or access to clearing transaction data. In particular, the clearing agency might have incentives to underinvest in the infrastructure necessary to provide clearing transaction data to its counterparties unless the Commission, by rule, were to establish minimum standards for communication of clearing transaction data from registered clearing agencies to their counterparties. As a result, counterparties could face greater difficulties in reporting data and an increased likelihood of incomplete, inaccurate, or untimely data being submitted to registered SDRs.

Third, under this alternative the registered clearing agency that is party to the transaction potentially has weaker incentives to provide high-quality regulatory data to the counterparty with a duty to report, which could reduce the quality of regulatory data collected by registered SDRs. The person with the duty to report a transaction has strong incentives to ensure that the transaction details are transmitted in a well-structured format with data fields clearly defined, and that contain data elements that are validated and free of errors because, pursuant to Regulation SBSR, this person is responsible for making accurate reports and, if necessary, making corrections to previously submitted data. Not only would the registered clearing agency have no duty under Regulation SBSR to provide information to its counterparty, but additionally, market forces might not provide sufficient motivation to the registered clearing agency to provide data to the counterparty in a manner that would minimize the counterparty's reporting burden. If registered clearing agencies exercise their market power against counterparties, the counterparties might have limited ability to demand high-quality data reporting services from registered clearing agencies and may require the services of agents that clean and validate transaction data that they receive.

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[948] Unless it preferred a particular registered SDR for operational reasons discussed above, a non-clearing-agency counterparty to a clearing transaction would likely contract with the clearing agency to report clearing transactions to the registered SDR that offers the lowest price, most likely the clearing agency affiliate. As discussed in Section II(B)(1), *supra*, a registered clearing agency and its affiliated SDR have greater control over the reporting process relative to sending transaction data to an independent SDR. This greater control lowers the cost of transmitting transaction data from the clearing agency to its affiliated SDR relative to transmitting the same data to an independent SDR. The lower cost potentially allows the affiliated SDR to charge the lowest price among competing SDRs.

[949] *See* Markit Letter at 12. Although the commenter asserts the benefits of allowing non-clearing agency counterparties discretion over which registered SDR receives their data in its assessment of Alternative 3, the Commission believes that this analysis applies equally to the assessment of Alternative 1.

[950] *See supra* note 948.

[951] *See* Regulation SBSR Proposed Amendments Release, 80 FR at 14782.

[952] *See* Markit Letter at 8.

The Commission believes, however, that despite a similarity in ultimate outcomes, and any benefits that might flow from enabling registered SDRs to compete for clearing transaction business, this alternative does not compare favorably to the adopted approach. As discussed above, assigning reporting obligations to the non-clearing-agency side could increase the number of reporting steps, thereby increasing the possibility of discrepancy, error, or delay in the reporting process. Placing the reporting duty on the non-clearing-agency side also could reduce data reliability if the data has to be reconfigured to be acceptable by the SDR. The Commission believes that discrepancies, errors, and delays are less likely to occur if the duty to report clearing transactions is assigned to registered clearing agencies directly, because there would be no additional or intermediate steps where data would have to be transferred or reconfigured.[953]

2. Alternative 2

A second, closely related alternative would involve placing registered clearing agencies within the Regulation SBSR reporting hierarchy, below registered security-based swap dealers and registered major security-based swap participants but above counterparties that are not registered with the Commission. Alternative 2 would assign the reporting obligation to a registered security-based swap dealer or registered major security-based swap participant when it is a counterparty to a registered clearing agency, while avoiding the need for non-registered persons to negotiate reporting obligations with registered clearing agencies.

As with Alternative 1, Alternative 2 potentially results in additional reporting steps and could marginally reduce the quality of regulatory data relative to the adopted approach. A key difference, however, is that Alternative 2 would reduce the likelihood of reporting obligations falling on unregistered persons, who would likely have less market power in negotiations with registered clearing agencies over the terms of reporting to a registered SDR. Larger counterparties, *i.e.*, those with greater transaction flow, would likely be better able to negotiate better terms by which clearing agencies report transactions on their behalf or provide the counterparties with access to the clearing data so that they can perform their own reporting.

In its discussion of Alternative 1, the Commission noted three particular ways in which limited competition among registered clearing agencies could result in poorer outcomes for non-clearing-agency counterparties. First, when these counterparties obtain clearing data from a registered clearing agency, they would likely incur any costs related to reformatting the data for submission to a registered SDR, including the costs of outsourcing these activities to an agent. Second, registered clearing agencies might charge these counterparties high fees for access to regulatory data that counterparties are required to submit to registered SDRs. Third, registered clearing agencies might have weak incentives to ensure that the data that they supply to non-clearing-agency counterparties are of high quality, since the non-clearing-agency counterparties would bear the costs of error correction.

Limiting the extent to which registered clearing agencies can exercise the market power resulting from limited competition over their counterparties could reduce some of the drawbacks to the Alternative 1. In particular, registered clearing agencies may be less likely to exercise market power in negotiations with larger market participants, particularly when these market participants are also clearing members. Clearing members play key roles in the governance and operation of registered clearing agencies, often contributing members of the board of directors. Moreover, clearing members contribute to risk management at registered clearing agencies by, for example, contributing to clearing funds that mutualize counterparty risk.[954] Nevertheless, the Commission believes that Alternative 2 does not fully address frictions that arise from limited competition among registered clearing agencies, such as high clearing fees or low quality services. The Commission believes that Alternative 2 would be less efficient than requiring the registered clearing agency to report the transaction information directly to a registered SDR, because the registered clearing agency is the only person who has complete information about a clearing transaction immediately upon its creation.

3. Alternative 3

The Commission considered a third alternative that would make the reporting side for the alpha responsible for reporting both the beta and gamma.[955] Alternative 3 would require the reporting side for the alpha also to report information about a security-based swap to which it is not a counterparty, *i.e.*, the clearing transaction between the registered clearing agency and the non-reporting side of the alpha. As discussed in Section III(B), *supra*, Alternative 3 would be operationally difficult to implement, could create confidentiality concerns, and could increase the likelihood of data discrepancy, error, and delay because Alternative 3 requires additional reporting steps. Alternative 3 also would require reporting sides to negotiate with registered clearing agencies to obtain transaction data and to bear the costs of correcting errors in these data, exposing them to the market power exercised by registered clearing agencies. Also, because the reporting side of the alpha would report the beta and gamma, Alternative 3 is premised on the view that the beta and gamma are life cycle events of the alpha. The Commission, however, considered and rejected this approach in the Regulation SBSR Adopting Release.

In addition, Alternative 3 could result in incomplete regulatory data because it could raise questions about who would report clearing transactions associated with the compression and netting of beta or gamma transactions. For example, suppose a non-dealer clears two standard contracts on the same reference entity using a single registered clearing agency, each contract having a different registered security-based swap dealer as counterparty. Under this alternative to the adopted approach, each dealer would be responsible for reporting a gamma security-based swap between the non-dealer and the registered clearing agency. However, this alternative does not specify which of four potential persons (the non-dealer, one or the two registered security-based swap dealers, or the clearing agency) would be required to report the contract that results from the netting of the two gamma security-based swaps between the non-dealer and the registered clearing agency.

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[953] *See supra* Section III(B).

[954] *See* Securities Exchange Act Release No. 68080 (October 22, 2013), 77 FR 66220, 66267 (November 2, 2012) (“Clearing Agency Standards Adopting Release”) (discussing financial resources of clearing agencies).

[955] The Commission considered and rejected this approach in the Regulation SBSR Adopting Release. *See* 80 FR at 14639 (“the new term ‘clearing transaction’ makes clear that security-based swaps that result from clearing (*e.g.*, betas and gammas in the agency model) are independent security-based swaps, not life cycle events of the security-based swap that is submitted to clearing (*e.g.*, alpha security-based swaps)”). However, the Commission is discussing this alternative in response to a commenter that, in response to the Regulation SBSR Proposed Amendments Release, recommended that the Commission adopt this approach. *See* Markit Letter at 11–13.

4. Commenter Views

One commenter proposed a fourth alternative to assigning reporting duties for cleared transactions.[956] Under this alternative, "the platform would remain the reporting side for all platform-executed trades while for bilateral or off platform cleared transactions, the reporting side would be the clearing agency. However, the clearing agency would be required to submit beta and gamma trade records to the alpha SDR (which would be determined by the alpha trade reporting side and not the clearing agency)." [957] For the reasons discussed above, the Commission considers this alternative less appropriate than the adopted approach.[958] While the Commission concurs with the approach of requiring the registered clearing agency to report the resulting beta and gamma transactions, the Commission believes that the registered clearing agency, when it has the duty to report security-based swaps, should be able to choose the registered SDR to which it reports.[959]

The same commenter stated that requiring registered clearing agencies to report their clearing transactions "is not supported by an adequate consideration of factors contained in Section 3(f) of [the Exchange Act]" and provided comments that focused on the proposed rule's "considerations of efficiency and competition." [960] Specifically, this commenter believed that the proposed rule "ignores the efficiency benefits and reduced costs introduced by middleware reporting agencies," and it "needlessly and unjustifiably proposes an approach to cleared [security-based swap] reporting that imposes a burden on competition." [961] Further, the commenter expressed the view that Rule 901(a)(2)(i) would deter competition based on service quality and cost in the market for SDR services, whereas the three alternatives would encourage such competition in the same market.[962] The Commission believes that it has adequately considered the factors contained in Section 3(f) of the Exchange Act in this release and in the Regulation SBSR Proposing Release.[963] Further, the Commission has evaluated four alternative allocations of reporting obligations, including their likely effects on efficiency and competition. The Commission appreciates the commenter's concern that competition in the market for SDR services could be hindered by Rule 901(a)(2)(i) with the possible result that clearing-agency-affiliated SDRs might charge higher fees and/or offer lower quality services to their users. However, the Commission notes that such effects on competition, should they occur, would be limited because Rule 13n–4(c)(1)(i) under the Exchange Act [964] requires an SDR, including a clearing-agency-affiliated SDR, to ensure that any dues, fees, or other charges imposed by, and any discounts or rebates offered by, the SDR are fair and reasonable and not unreasonably discriminatory. As noted in Section XIII, *supra,* an affiliated SDR might offer higher quality services and/or lower fees to its participants to the extent that the affiliated SDR realizes efficiency gains from vertical integration and shares some of these gains with its participants. Further, other commenters expressed the view that requiring registered clearing agencies to report clearing transactions could enhance market efficiency and improve the accuracy of reported data. Two commenters observed that clearing agencies will be able to leverage existing reporting processes and the existing infrastructure that they have in place with market participants and vendors to report clearing transactions.[965] Another commenter observed that requiring clearing agencies to report clearing transactions in security-based swaps would be "efficient, cost effective and promote[ ] global data consistency," because "clearing agencies have demonstrated their ability and preference to report data for cleared transactions" under swap data reporting rules established by the CFTC and in non-U.S. jurisdictions, including the European Union and Canada.[966] One commenter agreed with the Commission's preliminary view that proposed Rule 901(a)(2)(i) was superior to alternative reporting workflows that "could require a person who does not have information about [a] clearing transaction at the time of its creation to report that transaction." [967] As discussed above, the Commission acknowledges that Rule 901(a)(2)(i) could place a burden on competition in the market for clearing services and the market for security-based swap data reporting. However, the Commission rejects the commenter's view that the adopted approach needlessly and unjustifiably imposes a burden on competition. As discussed above, the Commission believes that the adopted approach is appropriate because it would eliminate additional steps in the reporting process that would be needed if another market participant were assigned the duty to report a clearing transaction or if the duty were to remain unassigned. By adopting a reporting methodology with as few steps as possible, the Commission intends to minimize potential delays, discrepancies, and errors in data transmission by assigning reporting duties to the person that holds the most complete and accurate information about clearing transactions at the moment of their creation.[968]

C. Reporting by Platforms

Pursuant to new Rule 901(a)(1), a platform is required to report a security-based swap transaction executed on that platform that will be submitted to clearing.[969] With the ability to clear security-based swap transactions, it is possible for two counterparties to trade anonymously on a platform. In an anonymous trade, because neither counterparty would be aware of the name or registration status of the other, it might not be possible for either counterparty to use the reporting hierarchy in existing Rule 901(a)(2)(i) to determine who would be required to report this alpha transaction.[970] The Commission is requiring a platform to report all alpha transactions executed on the platform that will be submitted to clearing, even those that might not be anonymous; this approach avoids the need for the platform and the counterparties to ascertain whether the counterparties are in fact unknown to each other.

Furthermore, the platform is the only entity at the time of execution—*i.e.,* before the transaction is submitted for clearing—that knows the identity of both sides. Requiring the platform to report information associated with transactions that will be submitted to clearing also reduces the number of data transmission steps between execution and reporting to a registered SDR. A platform that matches orders and executes transactions will possess or can readily obtain all of the primary trade information necessary to be reported to a registered SDR, and new Rule 901(a)(1) makes it unnecessary for counterparties to report these transactions. This approach is designed to result in a more efficient reporting process for platform-executed alphas. By reducing the number of steps between the creation of transaction data and reporting to a registered SDR, Rule 901(a)(1) reduces the possibility of data discrepancies and delays.

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[956] *See* Markit Letter at 13.

[957] *Id.*

[958] *See supra* Section III(B).

[959] *See supra* Section III(C).

[960] *See* Markit Letter at 3.

[961] *See id.* at 3–4.

[962] *See id.* at 12 (stating that "Proposed Rule 901(a)(2)(i) would deter competition for SDR and post-trade processing services and lower the utility of SDR services, since SDRs that are affiliated to clearing agencies and receive their reports for cleared SBS would no longer need to compete based on quality of service and cost, with no commensurate marginal benefit for market participants.") and 13 (stating that "these other alternatives, relative to the Proposal, encourage competition based on quality of service and cost and the rule of reporting agents and are more likely to result in outcomes whereby the same SDR will receive alpha, beta, and gamma trades").

[963] *See* Regulation SBSR Proposed Amendments Release, 80 FR at 14779–84.

[964] 17 CFR 240.13n–4(c)(1)(i).

[965] *See* ICE Letter at 5 (observing that, although the same systems could be used, they would need to be modified in certain respects); LCH.Clearnet Letter at 8.

[966] ISDA/SIFMA Letter at 24.

[967] Better Markets Letter at 4.

[968] *See supra* Section XII(A).

[969] *See supra* Section V.

[970] *See* Regulation SBSR Proposed Amendments Release, 80 FR at 14748–49.

While the level of security-based swap activity that currently takes place on platforms and is subsequently submitted for clearing is low, future rulemaking under Title VII could cause security-based swap trading volume on platforms to increase.[971] Efficiencies resulting from requiring platforms to report platform-executed alphas will increase to the extent that security-based swap trading volumes on platforms increases.

As discussed above in the context of reporting obligations for registered clearing agencies, the Commission believes that the reporting infrastructure costs associated with required reporting pursuant to the adopted amendments could represent a barrier to entry for new, smaller platforms that do not yet have the ability to report transactions to a registered SDR. To the extent that the adopted rules and amendments might deter new trading platforms from entering the security-based swap market, this could negatively impact competition.

1. Alternative Approaches to Reporting Platform-Executed Transactions

For platform-executed transactions that are submitted to clearing but are not anonymous, an alternative would be to use the reporting hierarchy in existing Rule 901(a)(2)(ii) to assign the reporting duty. Under such an alternative, a platform would have to determine which of the trades that it executes are anonymous and which are not, which would impose additional costs on platforms.[972] It is likely that platforms would seek to pass on these costs to its participants. The Commission believes that the due diligence that platforms would have to perform under this alternative would impose unnecessary costs without enhancing the benefits of regulatory reporting. Such costs can be avoided by requiring a platform to report all platform-executed alphas, which is what adopted Rule 901(a)(2)(i) requires.

A second alternative would be to assign the reporting duty for all platform-executed alphas to the registered clearing agency to which the alphas are submitted. While the registered clearing agency would likely have the information necessary for reporting—because the clearing agency will need much of the same information about the alpha to clear it—the Commission believes that it would be more appropriate to assign the reporting duty to the platform. This approach creates a more direct flow of information from the point of execution on the platform to the registered SDR, thus minimizing opportunities for data discrepancies or delays. This approach also avoids the need for the registered clearing agency to invest resources in systems to receive data elements from platforms beyond what is already required for clearing, and to report transactions to which it is not a counterparty.

D. Reporting of Clearing Transactions Involving Allocation

In the Regulation SBSR Adopting Release, the Commission explained the application of Regulation SBSR to bunched order executions that are not submitted to clearing.[973] In the Regulation SBSR Proposed Amendments Release, the Commission discussed the application of Regulation SBSR to bunched order executions that are submitted to clearing, and the security-based swaps that result from the allocation of the bunched order if the resulting security-based swaps are cleared. In this release, the Commission discusses how the amendments to Regulation SBSR that the Commission is adopting today apply to bunched order executions that are cleared. The discussion is designed to accommodate the various workflows that market participants employ to execute and allocate bunched order alphas. This guidance does not create any new duties under Regulation SBSR but does explain the application of Regulation SBSR to events that occur as part of the allocation process.[974] Additionally, because the guidance explains how Regulation SBSR applies to a platform-executed bunched order that will be submitted to clearing—and the security-based swaps that result from the allocation of any bunched order execution, if the resulting security-based swaps are cleared—the interpretation is not likely to have consequences for efficiency, competition, or capital formation beyond those stemming from imposing reporting obligations on registered clearing agencies and platforms, as discussed above in Sections II and III, respectively.

E. Application of Regulation SBSR to Prime Brokerage Transactions

In Section VII, *supra*, the Commission discussed how Regulation SBSR applies to security-based swaps arising out of prime brokerage arrangements. This guidance does not create any new duties; it merely explains how a series of security-based swaps arising from a prime brokerage arrangement should be reported and publicly disseminated under Regulation SBSR. Therefore, there are no additional costs or benefits beyond those already considered in the Regulation SBSR Adopting Release.[975]

A prime brokerage arrangement involves a reallocation of counterparty risk, as the prime broker interposes itself between its client and a third-party executing dealer. Regulatory reporting of each security-based swap leg will allow the Commission and other relevant authorities to more accurately conduct market surveillance and monitor counterparty risk. As a result of public dissemination of all security-based swaps arising from a prime brokerage arrangement, market observers will have access to information regarding each leg. This could help market observers infer from these disseminated reports the fees that the prime broker charges for its credit intermediation service and separate these fees from the transaction price of the security-based swap.

F. Prohibition of Fees and Usage Restrictions for Public Dissemination

New Rule 900(tt), as adopted herein, defines the term "widely accessible"—

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[971] The Commission has proposed, but not adopted, rules governing the registration and operation of SB SEFs. *See* SB SEF Proposing Release, 76 FR at 10948.

[972] There could be situations where a market participant splits an order into two or more child orders and some child orders are anonymously executed while other child orders are not anonymously executed. This could further complicate separation of anonymous and non-anonymous executions.

[973] *See* 80 FR at 14625–27.

[974] The Commission's estimates of events reportable under these amendments includes observable allocation by clearing agencies in the TIW data. Therefore, the costs associated with clearing transactions involving allocation are included in the Commission's estimate of the programmatic costs of Rules 901(a)(1) and (a)(2)(i).

[975] *See* 80 FR 14700–704. The Commission's estimates in that release of the total number of reportable events included all security-based swap legs arising out of prime brokerage arrangements.

which appears in the definition of "publicly disseminate" in existing Rule 900(cc)—to mean "widely available to users of the information on a non-fee basis." This new definition has the effect of prohibiting a registered SDR from charging fees for or imposing usage restrictions on the security-based swap transaction data that it is required to publicly disseminate under Regulation SBSR.

Allowing free and unrestricted access to the security-based swap data that registered SDRs are required to publicly disseminate is designed to reinforce the economic effects of public dissemination generally, because market observers will be able to enjoy the benefits of public dissemination without cost and without any restriction on how they use the disseminated data. Furthermore, new Rule 900(tt) reinforces the benefits of existing Rule 903(b), which provides that a registered SDR may utilize codes in the reported or disseminated data only if the information necessary to understand the codes is free and not subject to any usage restrictions. As the Commission pointed out in the Regulation SBSR Adopting Release, Rule 903(b) could improve the efficiency of data intake by registered SDRs and data analysis by relevant authorities and other users of security-based swap data; improve efficiency by minimizing operational risks arising from inconsistent identification of persons, units of persons, products, or transactions by counterparties; and promote competition by prohibiting fee-based licensing of reference information that could create barriers to entry into the security-based swap market.[976] If the Commission did not prohibit fees and usage restrictions relating to the publicly disseminated data, a registered SDR that wished to charge (or allow others to charge) users for the information necessary to understand these UICs—but could not, because of Rule 903(b)—might seek to do so indirectly by recharacterizing the charge as being for public dissemination. Such potential action by a registered SDR could reduce the economic benefits of Rule 903(b) and public dissemination generally. New Rule 900(tt) is designed in part to reinforce the economic effects, and help prevent avoidance, of Rule 903(b).

The adopted prohibition on a registered SDR charging fees for public dissemination of the regulatorily mandated security-based swap transaction data also is consistent with the CFTC's current prohibition on CFTC-registered swap data repositories charging for public dissemination of regulatorily mandated swap transaction data. Such consistency lessens the incentives for swap data repositories registered with the CFTC to enter the security-based swap market and also register with the Commission as SDRs and charge for public dissemination of security-based swap market data.[977] If the Commission did not take this approach, a CFTC-registered swap data repository could enter the security-based swap market and charge for public dissemination of security-based swap market data, and use revenues from this business to subsidize its operations in the swap market, where it is not permitted to charge for public dissemination of swap market data. If an SEC-registered SDR charges fees for security-based swap data to subsidize its reporting activity in the CFTC regime, then security-based swap market participants reporting to this SDR could face higher costs than those it would face if the SDR participated only in the security-based swap market.

The Commission recognizes that, because registered SDRs are prohibited from charging for the security-based swap data that Regulation SBSR requires them to publicly disseminate, they must obtain funds for their operating expenses through other means.[978] A registered SDR could pass the costs of publicly disseminating security-based swap data through to the persons who report transactions to the registered SDR. Direct fees imposed on market participants would likely be in proportion to the number of transactions they execute, with more active market participants, who contribute more to the production of transaction information, paying a larger share of the cost of disseminating that information. By contrast, it would be more difficult to equitably calibrate a fee based on the consumption of the publicly disseminated data, because it would be difficult to measure the intensity of a market observer's usage of the disseminated data. As the Commission discussed in the Regulation SBSR Adopting Release, the positive effects of public dissemination on efficiency, competition, and capital formation derive from the broad based use of disseminated data by a multitude of users.[979] There are likely to be a large number of marginal users of the disseminated data who would not obtain the data if they were required to pay for it. Thus, many potential users of the data might never have the opportunity to develop new uses for the data. While a funding model relying on fees for transaction reporting could result in security-based swap market participants subsidizing other users of security-based swap market data, charging fees for the consumption of publicly disseminated data could drastically reduce the number of data users and the associated positive effects on efficiency, competition, and capital formation.

The Commission notes that new Rule 900(tt) does not prohibit a registered SDR from offering value-added security-based swap market products for sale, provided that the SDR does not make transaction information available through the value-added product sooner than it publicly disseminates each individual transaction. This requirement is designed to prevent a registered SDR from obtaining an unfair competitive advantage over other firms that might wish to sell value-added market data products. Any such products could allow market observers to enjoy the positive impacts of Regulation SBSR on efficiency, competition, and capital formation more directly, by making it easier for market observers to understand the publicly disseminated data. Even if the SDR does not make transaction information available through the value-added product sooner than it publicly disseminates each individual transaction, the SDR retains a time advantage over a competing provider of value-added data products. This time advantage is the time taken for the SDR to electronically disseminate transaction information to the public. While the SDR has such a time advantage, the competitive effect of this advantage depends in part on the nature of the value-added data product. For value-added data products whose usefulness is not highly sensitive to data transmission time, such as a summary of monthly security-based swap trading activity, the SDR's time advantage would not exert a significant negative effect on other competitors. On the other hand, for value-added products whose usefulness decreases with data transmission time, such as a product that predicts security-based swap prices or volumes over the next minute, the SDR's time advantage could have a negative effect on other competitors. Even for such products, the SDR's time advantage would be limited if there are multiple competing SDRs accepting data in the same asset class and the SDR is offering a value-added product that requires not only the data that it accepts but also the data publicly disseminated by other competing SDRs. Any time advantage that the SDR might enjoy with respect to the data that it accepts could be offset by the absence of time advantage when receiving data publicly disseminated by other competing SDRs.

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[976] *See* 80 FR at 14723.

[977] Dual registration is likely to occur independent of the ability to charge for public dissemination of data in the security-based swap market. However, the ability to charge for public dissemination would add an additional incentive to do so.

[978] It is unlikely, however, in the absence of Rule 900(tt) that registered SDRs would have relied on charges for public dissemination as the sole means of funding their operations.

[979] *See* 80 FR 14720–22 (explaining how efficiency, competition, and capital formation could be enhanced when market participants, market observers, debt issuers, lenders, and business owners and managers, among others, make use of publicly disseminated security-based swap data).

G. Compliance Schedule for Regulation SBSR

The compliance schedule adopted in this release is designed to provide affected persons, especially registered SDRs and persons with a duty to report security-based swap transactions, with time to develop, test, and implement systems for carrying out their respective duties under Regulation SBSR. The new compliance schedule takes into consideration the fact that the CFTC's regulatory reporting and public dissemination rules are already in effect. As a result, several SDRs have provisionally registered and are operating in the swap market under CFTC rules, and swap market participants have developed substantial infrastructure to support swap transaction reporting. It is likely that participants in both the swap and security-based swap markets will seek to repurpose much of the infrastructure implemented in the swap market to support activities in the security-based swap market, which would enable more efficient implementation of the Commission's regime for security-based swap reporting.

Also, as discussed in Section X(C), *supra,* the new compliance schedule aligns Regulation SBSR compliance with security-based swap dealer registration. Thus, with respect to newly executed security-based swaps in a particular asset class, Compliance Date 1 for Rule 901 of Regulation SBSR is the first Monday that is the later of: (1) Six months after the date on which the first SDR that can accept transaction reports in that asset class registers with the Commission; or (2) one month after the SBS entities registration compliance date. Every security-based swap in that asset class that is executed on or after Compliance Date 1 must be reported in accordance with Rule 901. Compliance Date 2, when public dissemination shall commence, is the first Monday that is three months after Compliance Date 1. Compliance Date 3, by which all historical security-based swaps in that asset class must be reported to a registered SDR (to the extent that information about such transactions is available), is two months after Compliance Date 2.[980]

The proposed compliance schedule would have required affected persons to begin complying with Regulation SBSR before security-based swap dealers register with the Commission. A number of comments urged the Commission to delay Regulation SBSR compliance until after security-based swap dealers register.[981] One commenter provided extensive estimates of the costs that market participants could have incurred to develop reporting procedures for the Interim Period that likely would not have been applicable to the period after security-based swap dealer registration.[982] This commenter also pointed out that the Interim Period could create a competitive disadvantage for non-U.S. dealing entities because these entities could assume the responsibility but not the liability for reporting and thus might be less attractive to buy-side U.S. clients than U.S. dealing entities that could assume both the responsibility and liability for reporting.[983]

The Commission agrees with commenters that it would be more efficient for affected persons to focus on developing compliance procedures only for the period after security-based swap dealer registration, rather than require affected persons to expend resources to develop procedures for both the period after registration as well as for the Interim Period, because Interim Period procedures might be inapplicable to the period after registration. The Commission believes that, by eliminating the Interim Period and thus the need to expend resources for developing interim procedures, the adopted compliance schedule will promote efficiency. The adopted compliance schedule should also promote capital formation to the extent that persons that would have incurred reporting obligations during the Interim Period could invest the resources that would otherwise be expended in developing Interim Period procedures into productive assets.

Furthermore, the Commission acknowledges the commenters' concern that the Interim Period could create competitive disparities between U.S. and foreign dealing entities if buy-side U.S. persons were less willing to transact with foreign dealing entities if certain foreign dealing entities could not assume the liability for reporting. The adopted compliance schedule avoids the need for the Interim Period and thus eliminates any potential competitive disadvantage for foreign dealing entities described by the commenters. Thus, relative to the proposed compliance schedule, the adopted compliance schedule should promote competition among U.S. and foreign dealing entities that supply liquidity to the security-based swap market.

In summary, the Commission now believes, in light of the comments received on its proposal, that it would better promote efficiency, competition, and capital formation to delay compliance with the reporting obligations of Regulation SBSR until after the SBS entities registration compliance date.

The compliance schedule adopted herein also is based on the first SDR in an asset class to register with the Commission, which could confer a "first-mover advantage." [984] The first registered SDR could potentially capture a significant share of the SDR market because reporting parties, uncertain as to whether or when registration of other SDRs' applications might be granted, could feel compelled to onboard with the first registered SDR to secure sufficient time to prepare for Compliance Date 1.[985] Furthermore, the first registered SDR could hold on to its share of the SDR market for long periods if reporting persons that are connected to it face high costs of switching to a different registered SDR. Thus, the first mover advantage could potentially limit competition by making it more difficult for new SDR entrants to sign on reporting clients.

The Commission acknowledges that a first mover could emerge. Nevertheless, the Commission believes that, if one SDR application satisfies the criteria of Rule 13n–1(c)(3) under the Exchange Act before any others, it would not be appropriate for the Commission to delay granting its registration because of the status of other SDR applications.[986] The Commission continues to believe that most persons that have the desire and ability to operate as SEC-registered SDRs are already operational in the swaps market as swap data repositories provisionally registered with the CFTC, and each should have a strong incentive to submit applications to register with the Commission quickly.[987] Thus, there is less likelihood of multiple applications arriving over an extended period of time, and consequently, a lower likelihood of a first mover emerging.

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[980] Every security-based swap in that asset class that is executed on or after July 21, 2010, and up and including to the day immediately before Compliance Date 1 is a transitional security-based swap. As discussed in Section X(E), *infra,* the Commission's final compliance schedule establishes a separate Compliance Date 3 for the reporting of pre-enactment and transitional security-based swaps.

[981] *See* IIB Letter at 17; ISDA I at 4, 11–13; ISDA II at 1–14; ISDA III at 1–12; SIFMA–AMG II at 6–7; WMBAA Letter at 5–6; UBS Letter at 2.

[982] *See* ISDA III at 8–9.

[983] *See id.* at 3.

[984] *See* WMBAA Letter at 6; DTCC Letter at 12; SIFMA Letter at 17; DTCC/ICE/CME Letter at 4–5; ISDA/SIFMA Letter at 18.

[985] *See* DTCC Letter at 12; DTCC/ICE/CME Letter at 4–5; ISDA/SIFMA Letter at 18.

Even if a first mover emerges, other Commission rules are designed to minimize any potential of a monopoly advantage that the first SDR might otherwise enjoy. All SDRs, even the first or only registered SDR in a particular asset class, must offer fair, open, and not unreasonably discriminatory access to users of its services.[988] Moreover, any fees charged by an SDR must be fair and reasonable and not unreasonably discriminatory.[989]

The newly adopted compliance schedule could give added incentive to avoid delaying the submission of an application for registration as an SDR and to commence operation as an SEC-registered SDR as quickly as possible. This result would help the Commission and other relevant authorities obtain information about the security-based swap market for oversight purposes as quickly as possible, and also allow the public to obtain price, volume, and transaction information about all security-based swaps as quickly as possible.

As proposed in the Regulation SBSR Proposed Amendments Release, all historical security-based swaps in a particular asset class would have had to be reported to a registered SDR by proposed Compliance Date 1. As discussed in Section X(E), *supra,* the Commission has revised the compliance schedule to dissociate the requirement to report historical security-based swaps from Compliance Date 1. With respect to historical security-based swaps in a particular asset class, new Compliance Date 3 for the reporting of historical transactions is two months after Compliance Date 2, the date on which public dissemination commences. The Commission believes that the additional compliance delay for reporting historical security-based swaps represents an appropriate balancing of the benefits of mandatory reporting against the likely costs. Mandatory reporting of historical security-based swaps is generally less urgent than the reporting of newly executed transactions, particularly in light of the fact that most security-based swaps in the credit derivative asset class are already being reported on a voluntary basis to TIW. Because only available information about historical transactions must be reported, the Commission does not anticipate that reports of historical transactions made to registered SDRs will be significantly more informative than the reports already available through TIW.

Several commenters were concerned that requiring reporting pursuant to Regulation SBSR to begin before the Commission has made substituted compliance determinations "would impose significant and unnecessary burdens" on non-U.S. registered persons. Changes made by non-U.S. persons to their reporting infrastructure to comply with Regulation SBSR may not be necessary, in the commenters' views, if the Commission subsequently grants substituted compliance to these non-U.S. persons.[990] The Commission acknowledges the commenters' concern regarding burdens that may arise if compliance with Regulation SBSR precedes substituted compliance determinations. However, as discussed in Section X(C)(5), *supra,* the Commission does not believe that it is appropriate to defer compliance with Regulation SBSR until after the Commission makes one or more substituted compliance determinations. The Commission understands that changes made by non-U.S. persons to their reporting infrastructure to comply with Regulation SBSR might become unnecessary if substituted compliance is granted. However, these changes could be limited to the extent that the Commission and other jurisdictions require the collection and reporting of similar transaction information.

H. Amendments Related to Cross-Border Transactions

The amendments to Rules 901 and 908 adopted today will, among other things, apply Regulation SBSR's regulatory reporting and public dissemination requirements to all security-based swap transactions of a foreign dealing entity that are arranged, negotiated, or executed by U.S. personnel. Such ANE transactions are already subject to regulatory reporting and public dissemination if the other side includes a U.S. person. The amendments adopted today extend the regulatory reporting and public dissemination requirement to all ANE transactions, even if the other side is non-U.S. and not engaging in ANE activity. These amendments also for the first time assign the duty to report transactions between unregistered U.S. persons and unregistered non-U.S. persons. These amendments will have several effects on efficiency, competition, and capital formation in the U.S. financial market.

1. Competition

These amendments to Rules 901 and 908 will have implications for competition among market participants that intermediate transactions in security-based swaps as well as counterparties to security-based swaps. These amendments are designed to promote competition among liquidity providers in the security-based swap market by imposing consistent reporting and public dissemination requirements on both U.S. and foreign dealing entities, when the latter are engaging in ANE activity. If only U.S. dealing entities were subject to regulatory reporting and public dissemination requirements, the costs of these requirements would primarily affect U.S. dealing entities, their agents, and their counterparties. In contrast, foreign dealing entities and their agents, who might not be subject to comparable requirements in their home jurisdictions, could have a competitive advantage over U.S. dealing entities in serving unregistered non-U.S. counterparties using personnel located in a U.S. branch or office, were their activities not subject to the same requirements.[991]

These amendments to Rules 901 and 908 also are designed to promote competition between U.S. persons and non-U.S. persons that trade with foreign dealing entities, when a foreign dealing entity is utilizing U.S. personnel. A transaction between an unregistered foreign dealing entity engaging in ANE activity and a U.S. counterparty already is subject to regulatory reporting and public dissemination under existing Rule 908(a)(1)(i). In the absence of newly adopted Rules 901(a)(2)(ii)(E)(*2*) and (*3*), however, no one would be assigned to report such a transaction. Furthermore, in the absence of new Rule 908(b)(5), an unregistered foreign dealing entity engaged in an ANE transaction would not be subject to Regulation SBSR. This could create a competitive advantage for non-U.S. persons over similarly situated U.S. persons when they trade with foreign dealing entities. An unregistered foreign dealing entity might be able offer liquidity to a non-U.S. person at a lower price than to the U.S. person because the foreign dealing entity would not have to embed the potential costs of regulatory reporting and public dissemination into the price offered to the non-U.S. person. By contrast, the price offered by the unregistered foreign dealing entity to the U.S. person would likely reflect these additional costs, to the extent that public dissemination of a particular transaction imposes costs on the counterparties.[992] While the benefit of lower prices obtained by non-U.S. persons would depend on the magnitude of the perceived costs of public dissemination, the Commission believes that it is appropriate to place the transactions of U.S. persons and non-U.S. persons on a more equal footing, so that non-U.S. persons do not have a competitive advantage over U.S. persons when engaging in security-based swap transactions that, due to the involvement of U.S. personnel of the foreign dealing entity, exist at least in part within the United States.

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[986] *See supra* Section X(C)(4).

[987] *See* Regulation SBSR Proposed Amendments Release, 80 FR at 14786.

[988] *See* Rule 13n–4(c)(1)(iii) under the Exchange Act, 17 CFR 240.13n–4(c)(1)(iii).

[989] *See* Rule 13n–4(c)(1)(i) under the Exchange Act, 17 CFR 240.13n–4(c)(1)(i).

[990] *See* ISDA I at 15; ISDA/SIFMA Letter at 19; SIFMA/FSR Letter at 15.

[991] *See, e.g.,* Arnoud W.A. Boot, Silva Dezelan, and Todd T. Milbourn, "Regulatory Distortions in a Competitive Financial Services Industry," *Journal of Financial Services Research,* Vol. 17, No. 1 (2000) (showing that, in a simple industrial organization model of bank lending, a change in the cost of capital resulting from regulation results in a greater loss of profits when regulated banks face competition from unregulated banks than when regulations apply equally to all competitors).

The amendments to Rules 901 and 908 adopted herein also apply consistent regulatory reporting and public dissemination requirements to transactions between unregistered non-U.S. persons that are platform-executed or effected by or through registered broker-dealers. Because there will be very few such transactions, the Commission believes that the application of regulatory requirements is unlikely to generate competitive frictions between these different types of providers of intermediation services.[993]

As discussed in Section XII(B)(1)(2), *supra,* unregistered U.S. persons likely will seek to avoid the costs of assessing whether a foreign counterparty is engaging in ANE activity by choosing to transact only with registered entities for which assessment is not required. To the extent that unregistered U.S. persons avoid transacting with unregistered foreign dealing entities engaging in ANE activity in favor of transacting with registered entities, these foreign dealing entities could be at a competitive disadvantage when competing with registered entities to provide liquidity to unregistered U.S. persons. However, this competitive disadvantage could be limited if unregistered foreign dealing entities readily provide information on their use of U.S. personnel to unregistered U.S. persons who are potential counterparties, thereby obviating the need for the U.S. persons to conduct an assessment. Further, the competitive disadvantage could be eliminated entirely if a foreign dealing entity registers with the Commission as a security-based swap dealer. An unregistered foreign dealing entity that remains below the *de minimis* threshold may seek to register as a security-based swap dealer if the benefits from providing liquidity to unregistered U.S. persons are sufficient to justify the costs associated with dealer registration.

2. Efficiency

The Regulation SBSR Adopting Release did not address when an uncleared security-based swap involving only unregistered non-U.S. persons would be subject to regulatory reporting and/or public dissemination. The amendments to Rules 901 and 908 adopted herein, by requiring the public dissemination of ANE transactions, including those that are uncleared security-based swaps involving only unregistered non-U.S. persons, will increase price competition and price efficiency in the security-based swap market generally,[994] and enable all market participants to have more comprehensive information with which to make trading and valuation determinations for security-based swaps and related and underlying assets. The reporting of all ANE transactions to a registered SDR should enhance the Commission's ability to oversee security-based swap activity occurring within the United States and to monitor for compliance with specific Title VII requirements (including the requirement that a person register with the Commission as a security-based swap dealer if it exceeds the *de minimis* threshold). The reporting of these transactions likely will enhance the Commission's ability to monitor for manipulative and abusive practices involving security-based swap transactions or transactions in related underlying assets, such as corporate bonds or other securities transactions that result from dealing activity, or other relevant activity, in the U.S. market. The knowledge that the Commission and other relevant authorities are able to conduct surveillance on the basis of regulatory reporting could encourage greater participation in the security-based swap market since surveillance and the resulting increased probability of detection may deter potential market abuse. This could result in improved efficiency, due to the availability of more risk-sharing opportunities between market participants.

The Commission acknowledges the risk that, in response to the adopted amendments, foreign dealing entities, trading platforms, and/or registered broker-dealers could restructure their operations to avoid triggering requirements under Regulation SBSR. For example, a foreign dealing entity could restrict its U.S. personnel from intermediating transactions with non-U.S. persons, a trading platform might choose to move its principal place of business offshore, or a registered broker-dealer might cease to effect transactions in security-based swaps between unregistered non-U.S. persons. Such restructurings, if they occurred, could have an adverse effect on the efficiency of the security-based swap market by fragmenting liquidity between a U.S. security-based swap market—occupied by U.S. persons and non-U.S. persons willing to participate within the Title VII regulatory framework, with intermediation services provided by registered broker-dealers and U.S.-based trading platforms—and an offshore market in which participants seek to avoid any activity that could trigger application of Title VII to their security-based swap activity.[995] Such market fragmentation could reduce the amount of liquidity available to market participants whose activity is regulated by Title VII, increase their search costs, or erode any gains in price efficiency and allocative efficiency that might otherwise result from regulatory reporting and public dissemination of all security-based swap transactions that exist at least in part within the United States. If foreign dealing entities use only agents who are located outside the United States, there could be reduced competition in the market for security-based swap intermediation services and this smaller pool of competitors could in turn charge higher prices for intermediation. The result would be higher costs of searching for suitable counterparties. Higher search costs could in turn reduce the number of risk-sharing trades that foreign dealing entities execute and thus adversely affect risk-sharing efficiency in the security-based swap market broadly.

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[992] This effect would be diminished to the extent that a transaction of a foreign dealing entity is subject to public dissemination requirements under the rules of a foreign jurisdiction, and the costs of public dissemination are already factored into the prices offered to its counterparties.

[993] *See* U.S. Activity Proposal, 80 FR at 27501.

[994] *See* Regulation SBSR Adopting Release, 80 FR at 14720–21.

[995] *See* Cross-Border Adopting Release, 79 FR at 47364.

The Commission has already considered the likelihood that foreign dealing entities will cease using U.S. personnel to avoid Title VII requirements (such as security-based swap dealer registration).[996] The Commission continues to believe that market fragmentation that results from relocation of personnel is less likely because foreign dealing entities that elect to use such a strategy to avoid regulatory reporting requirements under Title VII also would bear the costs of restructuring their operations and potentially forgoing the benefits of access to local expertise in security-based swaps that are traded in the U.S. market.[997] Furthermore, the Commission believes that the amendments adopted herein, by extending Regulation SBSR to a small set of ANE transactions involving only non-U.S. persons and assigning the duty for reporting them, will impose only marginal burdens on platforms and registered broker-dealers.

3. Capital Formation

The amendments adopted herein could affect capital formation by affecting the transparency, liquidity, and stability of the market in which issuers seek capital. In the Regulation SBSR Adopting Release, the Commission identified benefits associated with the regulatory reporting and public dissemination of security-based swaps, such as increased transparency, improved liquidity, and greater market stability.[998] The Regulation SBSR Adopting Release did not impose any requirements on transactions between unregistered non-U.S. persons, even if one side was engaging in ANE activity. The amendments adopted in this release, by extending Regulation SBSR to all ANE transactions, should extend the benefits of regulatory reporting and public dissemination to all ANE transactions, which in turn could lead to more efficient allocation of capital by market participants and market observers.

The Commission recognizes that the amendments to Rules 901 and 908 adopted herein could impede capital formation by fragmenting the security-based swap market. As discussed in Section XIII(H)(2), *supra,* fragmentation of the security-based swap market could occur if market participants restructure their business activities by moving their personnel and operations offshore or restrict the counterparties to whom such persons may provide services. Such actions could impede capital formation because resources that market participants expend to restructure would not be available for investing in productive assets. Furthermore, fragmentation could create two separate security-based swap markets: A U.S. security-based swap market and an off-shore security-based swap market.[999] If fragmentation reduces the pool of market participants in the U.S. market, the market could experience lower trading activity and liquidity which in turn could reduce the ability of U.S. market participants to hedge financial and commercial risks and force them to put more resources into precautionary savings instead of investing those resources into productive assets.

However, as the Commission noted in Section XIII(H)(2), *supra,* the amendments adopted herein, by extending Regulation SBSR to all ANE transactions, will impose only marginal burdens on foreign dealing entities. The Commission does not believe that these limited burdens will cause foreign dealing entities to restructure their operations and fragment the security-based swap market such that capital formation would be adversely affected.

XIV. Regulatory Flexibility Act Certification

The Regulatory Flexibility Act ("RFA") requires federal agencies, in promulgating rules, to consider the impact of those rules on small entities. Section 603(a) of the Administrative Procedure Act,[1000] as amended by the RFA, generally requires the Commission to undertake a regulatory flexibility analysis of all proposed rules, or proposed rule amendments, to determine the impact of such rulemaking on "small entities."[1001] Section 605(b) of the RFA[1002] states that this requirement shall not apply to any proposed rule or proposed rule amendment which, if adopted, would not have a significant economic impact on a substantial number of small entities.

In developing the final rules contained in Regulation SBSR, the Commission has considered their potential impact on small entities. For purposes of Commission rulemaking in connection with the RFA, a small entity includes: (1) When used with reference to an "issuer" or a "person," other than an investment company, an "issuer" or "person" that, on the last day of its most recent fiscal year, had total assets of $5 million or less;[1003] or (2) a broker-dealer with total capital (net worth plus subordinated liabilities) of less than $500,000 on the date in the prior fiscal year as of which its audited financial statements were prepared pursuant to Rule 17a–5(d) under the Exchange Act,[1004] or, if not required to file such statements, a broker-dealer with total capital (net worth plus subordinated liabilities) of less than $500,000 on the last day of the preceding fiscal year (or in the time that it has been in business, if shorter); and is not affiliated with any person (other than a natural person) that is not a small business or small organization.[1005] Under the standards adopted by the Small Business Administration, small entities in the finance and insurance industry include the following: (1) For entities engaged in credit intermediation and related activities,[1006] entities with $550 million or less in assets; (2) for non-depository credit intermediation and certain other activities,[1007] entities engaged in non-depository credit intermediation and related activities, $38.5 million or less in annual receipts; (3) for entities engaged in financial investments and related activities,[1008] entities with $38.5 million or less in annual receipts; (4) for insurance carriers and entities engaged in related activities,[1009] entities with $38.5 million or less in annual receipts, or 1,500 employees for direct property and casualty insurance carriers; and (5) for funds, trusts, and other financial vehicles,[1010] entities with $32.5 million or less in annual receipts.

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[996] *See* U.S. Activity Adopting Release, 81 FR at 8629–30.

[997] *See id.* at 8633.

[998] *See* 80 FR at 14719–22.

[999] *See id.*

[1000] 5 U.S.C. 603(a).

[1001] Although Section 601(b) of the RFA defines the term "small entity," the statute permits agencies to formulate their own definitions. The Commission has adopted definitions of the term "small entity" for the purposes of Commission rulemaking in accordance with the RFA. Those definitions, as relevant to this proposed rulemaking, are set forth in Rule 0–10 under the Exchange Act, 17 CFR 240.0–10. *See* Securities Exchange Act Release No. 18451 (January 28, 1982), 47 FR 5215 (February 4, 1982) (File No. AS–305).

[1002] 5 U.S.C. 605(b).

[1003] *See* 17 CFR 240.0–10(a).

[1004] 17 CFR 240.17a–5(d).

[1005] *See* 17 CFR 240.0–10(c).

[1006] Including commercial banks, savings institutions, credit unions, firms involved in other depository credit intermediation, credit card issuing, sales financing, consumer lending, real estate credit, and international trade financing. *See* 13 CFR 121.201 at Subsector 522.

[1007] Including firms involved in secondary market financing, all other non-depository credit intermediation, mortgage and nonmortgage loan brokers, financial transactions processing, reserve, and clearing house activities, and other activities related to credit intermediation. *See* 13 CFR 121.201 at Subsector 522.

[1008] Including firms involved in investment banking and securities dealing, securities brokerage, commodity contracts dealing, commodity contracts brokerage, securities and commodity exchanges, miscellaneous intermediation, portfolio management, providing investment advice, trust, fiduciary and custody activities, and miscellaneous financial investment activities. *See* 13 CFR 121.201 at Subsector 523.

In the U.S. Activity Proposal, the Commission stated its belief that the majority of the amendments to Regulation SBSR proposed in that release would not have a significant economic impact on a substantial number of small entities for the purposes of the RFA.[1011] However, the Commission acknowledged that the proposed amendments would require a registered broker-dealer (including a registered SB SEF) to report a security-based swap transaction that is effected by or through it.[1012] The Commission further estimated that 30 registered broker-dealers (including SB SEFs) could be required to report such transactions, although the Commission was not able to estimate the number of those registered broker-dealers that would be "small entities."[1013] As a result, the Commission stated its preliminary belief that it is unlikely that these registered broker-dealers would be small entities and requested comment on the number of registered broker-dealers that are small entities that would be impacted by the proposed amendments, including any available empirical data.[1014]

In the Regulation SBSR Proposed Amendments Release, the Commission certified that the amendments proposed in that release would not have a significant economic impact on a substantial number of small entities for purposes of the RFA.[1015] The Commission believes, based on input from security-based swap market participants and its own information, that the majority of security-based swap transactions have at least one counterparty that is either a security-based swap dealer or major security-based swap participant, and that these entities—whether registered broker-dealers or not—would exceed the thresholds defining "small entities" set out above. The Commission continues to believe that the vast majority of, if not all, security-based swap transactions are between large entities for purposes of the RFA.

In addition, the Commission believes that persons that are likely to register as SDRs would not be small entities. Based on input from security-based swap market participants and its own information, the Commission continues to believe that most if not all registered SDRs will be part of large business entities, and that all registered SDRs will have assets in excess of the thresholds discussed above. Therefore, the Commission continues to believe that no registered SDRs will be small entities.

The Commission received no comments on the certification in the Regulation SBSR Proposed Amendments Release or, as indicated above, the Initial Regulatory Flexibility Analysis in the U.S. Activity Proposal. Accordingly, the Commission hereby certifies that the final rules adopted in this release will not have a significant impact on a substantial number of small entities for the purposes of the RFA.

XV. Statutory Basis

Pursuant to the Exchange Act, 15 U.S.C. 78a *et seq.*, and particularly Sections 3C(e), 11A(b), 13(m)(1), 13A(a), 23(a)(1), 30(c), and 36(a) thereof, 15 U.S.C. 78c–3(e), 78k–1(b), 78m(m)(1), 78m–1(a), 78w(a)(1), 78dd(c), and 78mm(a), the Commission is amending Rules 900, 901, 902, 905, 906, 907, and 908 of Regulation SBSR under the Exchange Act, 17 CFR 242.900, 242.901, 242.902, 242.905, 242.906, 242.907, and 242.908.

List of Subjects in 17 CFR Part 242

Brokers, Reporting and recordkeeping requirements, Securities.

Text of Amendments

In accordance with the foregoing, the Commission amends 17 CFR part 242 as follows:

PART 242—REGULATIONS M, SHO, ATS, AC, NMS, AND SBSR AND CUSTOMER MARGIN REQUIREMENTS FOR SECURITY FUTURES

■ 1. The authority citation for part 242 continues to read as follows:

Authority: 15 U.S.C. 77g, 77q(a), 77s(a), 78b, 78c, 78g(c)(2), 78i(a), 78j, 78k–l(c), 78*l*, 78m, 78n, 78o(b), 78o(c), 78o(g), 78q(a), 78q(b), 78q(h), 78w(a), 78dd–1, 78mm, 80a–23, 80a–29, and 80a–37.

■ 2. In § 242.900, revise paragraph (u) and add paragraph (tt) to read as follows:

§ 242.900 Definitions.

* * * * *

(u) *Participant,* with respect to a registered security-based swap data repository, means:

(1) A counterparty, that meets the criteria of § 242.908(b), of a security-based swap that is reported to that registered security-based swap data repository to satisfy an obligation under § 242.901(a);

(2) A platform that reports a security-based swap to that registered security-based swap data repository to satisfy an obligation under § 242.901(a);

(3) A registered clearing agency that is required to report to that registered security-based swap data repository whether or not it has accepted a security-based swap for clearing pursuant to § 242.901(e)(1)(ii); or

(4) A registered broker-dealer (including a registered security-based swap execution facility) that is required to report a security-based swap to that registered security-based swap data repository by § 242.901(a).

* * * * *

(tt) *Widely accessible,* as used in paragraph (cc) of this section, means widely available to users of the information on a non-fee basis.

■ 3. In § 242.901 add paragraphs (a)(1), (a)(2)(i), (a)(2)(ii)(E)(*2*) through (*4*), (a)(3), and (e)(1)(ii) and revise paragraphs (d)(4), (d)(8), (d)(9), (e)(2), and (h) to read as follows:

§ 242.901 Reporting obligations.

(a) * * *

(1) *Platform-executed security-based swaps that will be submitted to clearing.* If a security-based swap is executed on a platform and will be submitted to clearing, the platform on which the transaction was executed shall report to a registered security-based swap data repository the counterparty ID or the execution agent ID of each direct counterparty, as applicable, and the information set forth in paragraph (c) of this section (except that, with respect to paragraph (c)(5) of this section, the platform need indicate only if both direct counterparties are registered security-based swap dealers) and paragraphs (d)(9) and (10) of this section.

(2) * * *

(i) *Clearing transactions.* For a clearing transaction, the reporting side is the registered clearing agency that is a counterparty to the transaction.

(ii) * * *

(E) * * *

[1009] Including direct life insurance carriers, direct health and medical insurance carriers, direct property and casualty insurance carriers, direct title insurance carriers, other direct insurance (except life, health and medical) carriers, reinsurance carriers, insurance agencies and brokerages, claims adjusting, third party administration of insurance and pension funds, and all other insurance related activities. *See* 13 CFR 121.201 at Subsector 524.

[1010] Including pension funds, health and welfare funds, other insurance funds, open-end investment funds, trusts, estates, and agency accounts, real estate investment trusts and other financial vehicles. *See* 13 CFR 121.201 at Subsector 525.

[1011] *See* 80 FR at 27509.

[1012] *See id.*

[1013] *See id.*

[1014] *See id.*

[1015] *See* 80 FR at 14801.

(*2*) If one side includes a non-U.S. person that falls within § 242.908(b)(5) or a U.S. person and the other side includes a non-U.S. person that falls within § 242.908(b)(5), the sides shall select the reporting side.

(*3*) If one side includes only non-U.S. persons that do not fall within § 242.908(b)(5) and the other side includes a non-U.S. person that falls within § 242.908(b)(5) or a U.S. person, the side including a non-U.S. person that falls within § 242.908(b)(5) or a U.S. person shall be the reporting side.

(*4*) If neither side includes a U.S. person and neither side includes a non-U.S. person that falls within § 242.908(b)(5) but the security-based swap is effected by or through a registered broker-dealer (including a registered security-based swap execution facility), the registered broker-dealer (including a registered security-based swap execution facility) shall report the counterparty ID or the execution agent ID of each direct counterparty, as applicable, and the information set forth in paragraph (c) of this section (except that, with respect to paragraph (c)(5) of this section, the registered broker-dealer (including a registered security-based swap execution facility) need indicate only if both direct counterparties are registered security-based swap dealers) and paragraphs (d)(9) and (10) of this section.

(3) *Notification to registered clearing agency.* A person who, under paragraph (a)(1) or (a)(2)(ii) of this section, has a duty to report a security-based swap that has been submitted to clearing at a registered clearing agency shall promptly provide that registered clearing agency with the transaction ID of the submitted security-based swap and the identity of the registered security-based swap data repository to which the transaction will be reported or has been reported.

* * * * *

(d) * * *

(4) For a security-based swap that is not a clearing transaction and that will not be allocated after execution, the title and date of any master agreement, collateral agreement, margin agreement, or any other agreement incorporated by reference into the security-based swap contract;

* * * * *

(8) To the extent not provided pursuant to the other provisions of this paragraph (d), if the direct counterparties do not submit the security-based swap to clearing, a description of the settlement terms, including whether the security-based swap is cash-settled or physically settled, and the method for determining the settlement value;

(9) The platform ID, if applicable, or if a registered broker-dealer (including a registered security-based swap execution facility) is required to report the security-based swap by § 242.901(a)(2)(ii)(E)(*4*), the broker ID of that registered broker-dealer (including a registered security-based swap execution facility); and

* * * * *

(e) * * *

(1) * * *

(ii) *Acceptance for clearing.* A registered clearing agency shall report whether or not it has accepted a security-based swap for clearing.

(2) All reports of life cycle events and adjustments due to life cycle events shall, within the timeframe specified in paragraph (j) of this section, be reported to the entity to which the original security-based swap transaction will be reported or has been reported and shall include the transaction ID of the original transaction.

* * * * *

(h) *Format of reported information.* A person having a duty to report shall electronically transmit the information required under this section in a format required by the registered security-based swap data repository to which it reports.

* * * * *

■ 4. In § 242.902, revise paragraphs (c)(6) and (7) and add paragraph (c)(8) to read as follows:

§ 242.902 Public dissemination of transaction reports.

* * * * *

(c) * * *

(6) Any information regarding a clearing transaction that arises from the acceptance of a security-based swap for clearing by a registered clearing agency or that results from netting other clearing transactions;

(7) Any information regarding the allocation of a security-based swap; or

(8) Any information regarding a security-based swap that has been rejected from clearing or rejected by a prime broker if the original transaction report has not yet been publicly disseminated.

* * * * *

■ 5. In § 242.905, revise paragraph (a) to read as follows:

§ 242.905 Correction of errors in security-based swap information.

(a) *Duty to correct.* Any counterparty or other person having a duty to report a security-based swap that discovers an error in information previously reported pursuant to §§ 242.900 through 242.909 shall correct such error in accordance with the following procedures:

(1) If a person that was not the reporting side for a security-based swap transaction discovers an error in the information reported with respect to such security-based swap, that person shall promptly notify the person having the duty to report the security-based swap of the error; and

(2) If the person having the duty to report a security-based swap transaction discovers an error in the information reported with respect to a security-based swap, or receives notification from a counterparty of an error, such person shall promptly submit to the entity to which the security-based swap was originally reported an amended report pertaining to the original transaction report. If the person having the duty to report reported the initial transaction to a registered security-based swap data repository, such person shall submit an amended report to the registered security-based swap data repository in a manner consistent with the policies and procedures contemplated by § 242.907(a)(3).

* * * * *

■ 6. Revise § 242.906 to read as follows:

§ 242.906 Other duties of participants.

(a) *Identifying missing UIC information.* A registered security-based swap data repository shall identify any security-based swap reported to it for which the registered security-based swap data repository does not have the counterparty ID and (if applicable) the broker ID, branch ID, execution agent ID, trading desk ID, and trader ID of each direct counterparty. Once a day, the registered security-based swap data repository shall send a report to each participant of the registered security-based swap data repository or, if applicable, an execution agent, identifying, for each security-based swap to which that participant is a counterparty, the security-based swap(s) for which the registered security-based swap data repository lacks counterparty ID and (if applicable) broker ID, branch ID, execution agent ID, trading desk ID, and trader ID. A participant of a registered security-based swap data repository that receives such a report shall provide the missing information with respect to its side of each security-based swap referenced in the report to the registered security-based swap data repository within 24 hours.

(b) *Duty to provide ultimate parent and affiliate information.* Each participant of a registered security-based swap data repository that is not a platform, a registered clearing agency, an externally managed investment vehicle, or a registered broker-dealer (including a registered security-based swap execution facility) that becomes a participant solely as a result of making a report to satisfy an obligation under § 242.901(a)(2)(ii)(E)(*4*) shall provide to the registered security-based swap data repository information sufficient to identify its ultimate parent(s) and any affiliate(s) of the participant that also are participants of the registered security-based swap data repository, using ultimate parent IDs and counterparty IDs. Any such participant shall promptly notify the registered security-based swap data repository of any changes to that information.

(c) *Policies and procedures to support reporting compliance.* Each participant of a registered security-based swap data repository that is a registered security-based swap dealer, registered major security-based swap participant, registered clearing agency, platform, or registered broker-dealer (including a registered security-based swap execution facility) that becomes a participant solely as a result of making a report to satisfy an obligation under § 242.901(a)(2)(ii)(E)(*4*) shall establish, maintain, and enforce written policies and procedures that are reasonably designed to ensure that it complies with any obligations to report information to a registered security-based swap data repository in a manner consistent with §§ 242.900 through 242.909. Each such participant shall review and update its policies and procedures at least annually.

■ 7. In § 242.907, revise paragraph (a)(6) to read as follows:

§ 242.907 Policies and procedures of registered security-based swap data repositories.

(a) * * *

(6) For periodically obtaining from each participant other than a platform, registered clearing agency, externally managed investment vehicle, or registered broker-dealer (including a registered security-based swap execution facility) that becomes a participant solely as a result of making a report to satisfy an obligation under § 242.901(a)(2)(ii)(E)(*4*) information that identifies the participant's ultimate parent(s) and any participant(s) with which the participant is affiliated, using ultimate parent IDs and counterparty IDs.

* * * * *

■ 8. In § 242.908:

■ a. Amend paragraph (a)(1)(i) by removing the "or" at the end of the paragraph;

■ b. Amend paragraph (a)(1)(ii) by removing the period at the end of the paragraph and adding in its place a semicolon;

■ c. Add paragraphs (a)(1)(iii) through (v);

■ d. Revise paragraphs (b)(1) and (2); and

■ e. Add paragraphs (b)(3) through (5).

The revisions and additions read as follows:

§ 242.908 Cross-border matters.

(a) * * *

(1) * * *

(iii) The security-based swap is executed on a platform having its principal place of business in the United States;

(iv) The security-based swap is effected by or through a registered broker-dealer (including a registered security-based swap execution facility); or

(v) The transaction is connected with a non-U.S. person's security-based swap dealing activity and is arranged, negotiated, or executed by personnel of such non-U.S. person located in a U.S. branch or office, or by personnel of an agent of such non-U.S. person located in a U.S. branch or office.

* * * * *

(b) * * *

(1) A U.S. person;

(2) A registered security-based swap dealer or registered major security-based swap participant;

(3) A platform;

(4) A registered clearing agency; or

(5) A non-U.S. person that, in connection with such person's security-based swap dealing activity, arranged, negotiated, or executed the security-based swap using its personnel located in a U.S. branch or office, or using personnel of an agent located in a U.S. branch or office.

* * * * *

By the Commission.

Dated: July 14, 2016.

Jill M. Peterson,

Assistant Secretary.

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7 CFR Part 400

Submission of Policies, Provisions of Policies, Rates of Premium, and Non-Reinsured Supplemental Policies; Final Rule

DEPARTMENT OF AGRICULTURE

Federal Crop Insurance Corporation

7 CFR Part 400

[Docket No. FCIC–13–0006]

RIN 0563–AC46

Submission of Policies, Provisions of Policies, Rates of Premium, and Non-Reinsured Supplemental Policies

AGENCY: Federal Crop Insurance Corporation, USDA.

ACTION: Final rule.

SUMMARY: The Federal Crop Insurance Corporation (FCIC) finalizes the General Administrative Regulation—Subpart V—Submission of Policies, Provisions of Policies, Rates of Premium, and Non-Reinsured Supplemental Policies. The intended effect of this action is to incorporate legislative changes to the Federal Crop Insurance Act (Act) stemming from the Agricultural Act of 2014, clarify existing regulations, lessen the burden on submitters of crop insurance policies, provisions of policies, or rates of premium under section 508(h) of the Act, provide guidance on the submission and payment for concept proposals under section 522 of the Act, provide provisions for submission and approval of index-based weather plans of insurance as authorized by section 523(i) of the Act, and to incorporate changes that are consistent with those made in the Common Crop Insurance Policy Basic Provisions (Basic Provisions).

DATES: This rule is effective September 12, 2016.

FOR FURTHER INFORMATION CONTACT: Tim Hoffmann, Product Administration and Standards Division, Risk Management Agency, United States Department of Agriculture, Beacon Facility, Stop 0812, Room 421, P.O. Box 419205, Kansas City, MO 64141–6205, telephone (816) 926–7730.

SUPPLEMENTARY INFORMATION:

Background

This rule finalizes changes to the General Administrative Regulation—Subpart V—Submission of Policies, Provisions of Policies, Rates of Premium, and Non-Reinsured Supplemental Policies (7 CFR part 400, subpart V), that were published by FCIC on February 25, 2015, as a notice of proposed rulemaking in the **Federal Register** at 80 FR 10008—10022. The public was afforded 60 days to submit comments after the regulation was published in the **Federal Register.**

A total of 80 comments were received from 10 commenters. The commenters were insurance providers, insurance organizations, grower organizations, crop insurance product developers, and a business council.

The public comments received regarding the proposed rule and FCIC's responses to the comments are as follows:

General

Comment: A commenter stated they believe the 508(h) process serves agriculture well. The commenter believes Congress intended the 508(h) process to protect the best interest of most growers through inclusion in the farm bill. As the size of government shrinks, the ability to engage the private sector in creating functional insurance products will grow. In serving the American farmer, and to be consistent with the farm bill, RMA should seek a vibrant and functional regulation that will encourage development of insurance products. A clear regulation would be a step in the right direction.

Response: FCIC agrees with the commenter that the regulation should be written as clearly as possible. FCIC has made a number of changes in the final rule to clarify provisions in the regulation.

Comment: A commenter offered support for the proposed rule. The commenter stated they believe that under the current rules, smaller farmers and organizations are placed at a competitive disadvantage compared to large corporate farms due to the current procedures favoring these bigger businesses. The commenter stated they believe that under the current proposal, these procedures would be simplified to facilitate increased access to FCIC's services by smaller farmers, commodity groups, and others to make it easier for these producers to develop brand new programs. In that light, the commenter also favors the expansion of FCIC's current programs in western Washington to include many crops which are classed as specialty crops and currently not covered by FCIC. The commenter stated they value their agricultural industry in western Washington and the working relationship they have with many of the local farmers. Moreover, the commenter stated they are committed to supporting the small agricultural industry and continuing to work with farmers, especially at the individual and small producer level, in addressing collective interests. The commenter sees the proposed simplification of the procedures and expansion of crops covered as positive and vital steps in a direction that encourages the smaller agricultural businesses in their region.

Response: FCIC appreciates the commenter's support for the Federal crop insurance program.

Comment: A commenter offered a general concern with the 508(h) process, which is that any individual or organization can submit a proposal following the guidelines in these regulations even if they do not plan to write or retain any of the risk for the proposed program. While the submitter must have a commitment in writing from at least one approved insurance provider (AIP) to sell and support the policy or plan of insurance, this is often very informal and the supporting AIP will generally have little or no involvement in the development process of such product. These developers establish all of the terms, conditions, and rates for the proposed program, but often have no exposure to the actual results that may occur from the product that is developed. The AIPs who choose to participate in these approved 508(h) submissions retain the risk for such coverages and suffer the consequences of any flaws or deficiencies that may exist with them. The commenter proposed that the FCIC should allow the opportunity for AIPs who choose to participate in writing these approved 508(h) submissions to reduce their risk exposure for these programs beyond what is currently allowed during the initial years until a credible number of years of experience have been developed to determine the adequacy of the program from both an underwriting and rating standpoint.

Response: FCIC agrees that the current regulations do not contain enough involvement of the AIP in the development process or consideration of the impact of the submission on other AIPs and the delivery system. As a result, FCIC is adding provisions that require a more formal involvement by an AIP in the development process, requiring that an AIP be included as a submitter, and having that AIP and one other independent AIP provide an assessment of marketability, risks, and anticipated impacts on the delivery system. With respect to the risks, AIPs can independently assess the potential risk of a privately developed policy, and based on their own assessment, may choose whether or not to sell the product. AIPs have the option to reduce their risk exposure by assigning higher risk policies to the Assigned Risk Fund under the Standard Reinsurance Agreement (SRA), a fund that significantly limits risk exposure to the AIP and transfers that risk to FCIC.

Comment: A commenter stated that this regulation incorporates language to address the index-based weather plans of insurance, which were authorized by the Agricultural Act of 2014 (2014 Farm Bill). One of the requirements for these products is that they must first be approved by the applicable regulatory authority for the state in which the AIP intends to offer the product. The commenter stated their understanding is that there are currently no states that will approve these type of products as they are considered to be derivative products whereby the product may allow a loss payment to be made even though no physical damage to the crop has occurred. If no states will approve such products, this effectively makes the additional language addressing such index-based weather plans of insurance meaningless. The commenter recommended that the RMA consider not including any reference to index-based weather plans of insurance until such time that a state regulatory authority will approve a product of this nature. Otherwise, the portion of the regulation related to index-based weather products is not implementable.

Response: The proposed rule required that index-based weather plans of insurance must first be approved by the state in which they will be sold prior to FCIC approval. This provision is necessary because these products are not reinsured by FCIC, so the provisions regarding Federal preemption do not apply. Each state will be required to regulate the sale and service of these index-based weather plans of insurance. Regardless of whether any states have previously approved any index-based weather plans of insurance, FCIC is obligated to implement the process for submitting, reviewing, approving, and implementing these products in accordance with the Federal Crop Insurance Act because states may elect to approve such plans of insurance in the future. In such case, for any index-based weather plan of insurance that may be approved by a state, the process to submit, review, approve, and implement such plans of insurance will timely be in place.

§ 400.701—Definitions

Comment: A commenter stated that the definition of "advanced payment" as proposed, could be read to allow 50 percent of the development cost after the applicant has begun research and development activities. The commenter contends the intent of the definition is to allow an additional 25 percent advance payment after research and development activities are underway. The phrase "after the applicant has begun research and development" should be moved to the end of the definition to eliminate any possible confusion.

Response: FCIC agrees with the commenter and moved the phrase to prevent possible confusion. In addition, FCIC added the 25 percent advance payment requirements from the Federal Crop Insurance Act. These requirements are as follows: (1) The concept proposal will provide coverage for a region or crop that is underserved, including specialty crops; and (2) the submitter is making satisfactory progress towards developing a viable and marketable 508(h) submission. FCIC intended to include these requirements in the Procedures Handbook 17030—Approved Procedures for Submission of Concept Proposals Seeking Advance Payment of Research and Development Costs, but determined it more appropriate to include these in this regulation. However, the evidence necessary to show satisfactory progress, or to determine if the crop or region is underserved, may be included in the Procedures Handbook 17030—Approved Procedures for Submission of Concept Proposals Seeking Advance Payment of Research and Development Costs.

Comment: A commenter stated that the definition of the term "complete" is confusing or subjective. The commenter stated the definition of complete in § 400.701 attempts to redefine the word to include unrelated subjects. This can be very confusing, especially because the word complete is hardly a term of art. A better definition of complete would be found in any dictionary. The commenter suggested a 508(h) submission be considered either complete or not complete (although the commenter suggested materiality should be considered) if it contains the required elements in § 400.705. The term "sufficient quality" is included within the definition of complete, but is a performance standard. Performance standards are better placed within § 400.705. The inclusion of performance standards within a definition is suspect. Significant effort will be expended to develop concept proposals and 508(h) submissions. In fact, it is a very reasonable assumption that the submitting public will invest tens of thousands of hours (if not hundreds of thousands of hours) in efforts to improve the crop insurance system under this rule. FCIC can support the improvements certain to come out of the private sector by expending relatively small efforts to clearly codify its notion as to what is sufficient quality. The term "meaningful" is subjective and should also be removed from the definition. Meaningful should also be described within § 400.705. The commenter suggested the following revised definition of complete: "a submission, concept proposal, or index-based weather plan of insurance that contains all required documentation shown at § 400.705."

Response: FCIC disagrees with the commenter that the definition of "complete" is subjective. The definition relies on submitters meeting the requirements in § 400.705 and the submission must be of "sufficient quality" as defined in § 400.701. Sufficient quality is not a performance standard so much as it is a determination of whether there is adequate information to consider the submission comprehensive enough and complete to allow for a meaningful external reviewer to provide their assessment of the product submitted. The main purpose of a determination of completeness is to determine whether to send the submission for external expert review. Therefore, in addition to providing the required information, it is also necessary that the information provided is of sufficient quality in order for external expert reviewers to conduct a meaningful review and be able to determine if the 508(h) submission meets the standards for approval by the Board. There is a cost for external reviews so sufficient quality of a 508(h) submission is an important consideration for quality external expert reviews that provide the Board with meaningful feedback and analysis, and make prudent use of public funds. The definition in the dictionary would be insufficient to evaluate the information necessary to determine completeness. No change has been made.

Comment: A commenter stated that the definition of "complexity" should be eliminated from the final rule. A developer's notion of complexity has little to do with any of the factors considered in the proposed rule. Underwriting complexity arises from the identification and treatment of risk. Tying complexity to the format of existing crop insurance policy materials is naïve. Actuarial complexity resides with the types, quantity and quality of available price and yield data. Crops with significant recorded histories are significantly easier to work with than crops with sparse or scattered data. The proposed methodology has little to do with a complexity determination. In addition, the complexity determination seems to be a discriminatory tool placed against grower organizations needing crop insurance programs. The complexity determination can and will discourage developers from treating specialty crop insurable risks. Whereas the generally accepted notion of a professional risk manager is to reduce risk, the complexity determination is certain to increase risk for developers precisely where an insurance treatment of risk is often needed. The commenter concludes that the discriminatory complexity determination should be eliminated from the final rule so that all grower groups have equal access to the benefits of crop insurance.

Response: FCIC disagrees with the commenter that the definition of "complexity" should be removed. First, the Board is required to consider complexity when assessing the reimbursement of costs under section 522(b)(6) of the Act. Therefore, a standard for determining complexity is required. Second, this provision is neither intended nor expected to discourage development of products for specialty crops. However, the use of the term "processes" is unclear and the term has been removed in the final rule and replaced with the phrase "all other steps required." FCIC recognizes the complexity of a product should be reflected in the level of effort it takes to complete a particular submission requirement. The purpose of these provisions is to protect taxpayer dollars by reimbursing developers appropriate amounts to reflect the level of effort and work performed. This allows distinctions to be made between submissions that may simply add a new coverage to an existing policy without changing the policy terms, underwriting, or premium rating and submissions that create whole new plans of insurance that measure risk differently than the yield or revenue based policies available under the Common Crop Insurance Policy (7 CFR part 457) and the Area Risk Protection Policy (7 CFR part 407). Completely new plans of insurance may require new underwriting and loss adjustment handbooks or premium rating methodology and that will be reflected in the research and development for the submission. Presently, regardless of the type of submission, most requests are generally near the same dollar amount, even though the level of work required may not be the same. This gives the Board the discretion to reduce payments to submissions where the costs seem excessive for the amount of work needed. FCIC is revising the provisions in § 400.712(e) by removing the percentage reductions for complexity and scope and giving the Board discretion to make adjustments as required by the Federal Crop Insurance Act based on type of submission and amount of work required and the size of the area proposed to be covered.

Comment: A commenter stated that the definition of "concept proposal" stretches into evaluative criteria. The definition introduces a new concept, "enough information." This section of the proposed rule should be limited to the section title, "Definitions." A more accurate definition would be: "A written proposal for the funding of research and development of a crop insurance plan that will comply with the provisions of this rule and authorized by section 522 of the Act." Whether the concept proposal is complete or of sufficient quality are evaluative criteria best managed in their proper location (§ 400.705) and not within the definitions section.

Response: FCIC agrees with the commenter that the proposed use of the phrase "enough information" in the definition of "concept proposal" is vague and subjective. A better approach would be to reference where the required information is contained. FCIC has revised the definition by removing the phrase "enough information" and replacing it with a reference to this regulation and the Procedures Handbook 17030—Approved Procedures for Submission of Concept Proposals Seeking Advance Payment of Research and Development Costs, which can be found on the RMA Web site at *www.rma.usda.gov.*

Comment: A few commenters stated that the definition of "delivery system" should be modified. One commenter stated that the phrase "but is not limited to" is not a necessary component of the definition and recommended that the phrase be removed from the definition of "delivery system." Several commenters stated that this definition would undermine the private-public partnership that has been the cornerstone of Federal Crop Insurance for 35 years. One of the commenters suggested this definition be stricken from the proposed rule. The commenter stated that when the United States Congress and American agriculture have placed so much responsibility and confidence in Federal Crop Insurance and just recently emphasized and renewed their trust in the context of the 2014 Farm Bill, this provision of the rule, which could very well be used to undermine the entire system, is both perplexing and especially ill-timed.

Response: Congress expressly requires the Board to consider the potential impact on the delivery system. Therefore, a definition of "delivery system" is necessary. Consistent with section 508(a)(4)(C) of the Act, the delivery system includes the AIPs. However, there are numerous other entities that are necessary to sell and service policies to producers. Therefore, FCIC agrees with the commenter that the second sentence containing the phrase "includes but is not limited to" is not necessary. Therefore, the definition has been retained in the final rule, but the second sentence has been removed.

Comment: A commenter stated that portions of the definition of "maintenance," regarding the addition of a new commodity and concept proposals that are similar to a previously approved 508(h) submission, should be removed. The commenter stated that it seems new insured crops and new concept proposals should be eligible for advance payments and a full four reinsurance years of maintenance expenses in accordance with the Act. The portion of the definition that considers expanding a 508(h) program maintenance, restricts the ability of farmers to receive the benefits of crop insurance. The result is discriminatory because it prevents developers from expanding a program into a new area if the program is successful. For example, developers manage their risk by limiting the scope of the program. USDA rules, rather than encouraging the expansion of crop insurance, in fact cause developers to cautiously approach the development problem. For a developer, risk management may involve limiting the scope of the program to avoid the potential financial losses from having the current arbitrary standards, and the increasingly arbitrary standards shown in this proposed rule, reducing their operating capital. This is particularly a problem given the Board's resistance to expanding approved 508(h) products into other territories due to an over-cautious approach on the part of the Board and a failure to understand the substantive risk the 508(h) process presents to developers. Unfortunately, with this regulation, including this definition of maintenance, the FCIC continues to pressure developers, with the result being fewer growers served by the insurance program.

Response: FCIC disagrees with the commenter that the language in the definition of "maintenance" regarding the addition of a new commodity and concept proposals should be removed. FCIC disagrees this language is discriminatory and arbitrary. The language does not prevent the expansion or reimbursement for expanding approved products, but rather it prevents the inappropriate use of limited funds for activities that require little additional effort, work, or development on the part of the submitter to add additional commodities similar in nature and scope. To the extent that added costs are incurred during an expansion, the submitter is able to request reimbursement of such costs in the maintenance reimbursement. No change made in the final rule.

Comment: A commenter stated the definition of "marketing plan" is unnecessary and only serves to confuse reviewers and submitters. A marketing plan is a submission requirement listed in § 400.705. The definition of a marketing plan is redundant and should be struck from the final rule. All requirements for a marketing plan, including a standard for sufficient quality, should be shown in the regulatory language requiring the marketing plan.

Response: FCIC agrees the definition of "marketing plan" is somewhat repetitive because much of the information is contained in § 400.705(e) and does not really capture the information that is required to assess the potential marketability of a submission. Since the enactment of the 2014 Farm Bill, marketability is a standard used by the Board in determining whether to approve a submission. Previously, marketability was only considered in the reimbursement of research and development costs. Therefore, FCIC has changed the term to "marketability assessment" to more accurately reflect the information necessary. FCIC has also removed the definition and moved the substantive provisions to § 400.705(e).

Comment: Several commenters were concerned the definition of the term "sufficient quality" could be interpreted as subjective, confusing, and contains performance standards. The commenters stated that the definition should be transparent, concrete and reasonable. The commenters proposed FCIC revisit the terminology and publish in the final rule definitions that provide clear and measurable standards that can be met by a submitter. One commenter suggested the definition of "sufficient quality" should be stricken from the final rule and an actual standard placed with the requirement in § 400.705. A commenter stated the requirement that "The material book must be presented in Microsoft Office format . . ." is a submission requirement that belongs in § 400.703—Timing and Format. A commenter stated the phrase "must contain adequate information for determination to be made whether RMA has the resources to implement, administer and deliver" is a performance standard that should be contained in § 400.705—Contents for New and Changed Submissions. The commenter stated it seems unlikely that any submitter should be placed in the position of attempting to determine whether FCIC can implement any particular product. Although it seems logical that confusing regulations should be interpreted against the author, when a regulation is confusing, it is likely to be held against the submitter. Under this proposed rule, even if a submitter complies with a reasonable interpretation of the submission requirement and its evaluative standard, the 508(h) submission could be judged as being of insufficient quality. To complicate a regulation with confusing, arbitrary and subjective language is a disservice to the farmers and ranchers whose financial well-being provides purpose for the crop insurance program. The expectation of the FCIC should be described using objective standards so submitters' efforts can match the standard. The lack of a clear definition for sufficient quality allows for arbitrary and possibly even discriminatory decisions. Because there is no clear standard and many of the decisions of the Board are made "at the sole discretion of the Board or RMA," the proposed rule invites disparate treatment of submitters. The final rule should be drafted with clear standards to create a level playing field for all submitters. Because there are only about 12 places where sufficient quality needs to be defined, the commenter strongly encouraged FCIC to expend effort to place its concept of sufficient quality into § 400.705.

Response: FCIC agrees the performance standards included in the proposed definition of "sufficient quality" should be located in § 400.705 so that the submitter is aware of the standards by which the product will be measured. FCIC disagrees that the definition of "sufficient quality" should be removed because it is confusing or subjective. The definition of "sufficient quality" is necessarily subjective because each submission is different, and an objective one-size-fits-all definition would do a disservice to unique submissions that may differ substantially from others. Further, the purpose of the term "sufficient quality" is to ensure that there is sufficient data and analysis to support the provisions in the concept or submission, and that the submission is clear, so the Board, RMA, and external expert reviewers can evaluate the submission to determine whether it meets the qualifications for approval. Therefore, the Board, RMA, and external expert reviewers must be able to understand what the submitter has done and why and draw conclusions based on the data, analysis and information provided by the submitter. The definition has been simplified to reflect this, and FCIC removed the reference to, and definition of "disinterested third party" because it is really the external expert reviewers, RMA and the Board who have to evaluate concept proposals and submissions. FCIC has also revised the definition of "sufficient quality" to clarify the determination is made by RMA and the Board. FCIC agrees the requirement in the definition of "sufficient quality" for the material to be presented in Microsoft Office format can be removed because this requirement is contained in § 400.705. FCIC has also added a reference to the Plain Writing Act of 2010 in order to clarify the "clearly written" requirement.

Comment: A few commenters stated that the definition of "viable and marketable" should be clearer and contain the qualities and standards to be applied. One commenter states the definition of viable and marketable provides for a determination by the Board. The commenter suggested that the determination of viable and marketable should be clear enough so a submitter is able to arrive at the same conclusion as the Board or external expert reviewers regarding the marketability of the proposed product. The lack of a standard is certain to provide divergent views between submitters, the Board, RMA, and the external expert reviewers. Given the number of entities involved in this process and the difficulties and costs involved in producing a 508(h) submission, FCIC should include a clear definition of viable and marketable in the final rule. A commenter stated that the proposed definition of viable and marketable addresses neither viable nor marketable and should be removed in the final rule.

Response: Consideration of whether a submission is "viable and marketable" is required by the Act. The requirements of the Act cannot be waived by this regulation. However, to be clearer, separate definitions are provided for "viable" and "marketable" to reflect the different concepts embodied in each. With respect to marketability, the Board is specifically tasked with making the determination of whether or not a sufficient number of producers will purchase the product to justify the resources and expenses required to offer the product for sale and maintain the product for subsequent years. There is no specific number of producers or dollar amount that could be included in the definition that would be appropriate for all scenarios. Therefore, it is necessary to give discretion to the Board to make this determination. With respect to viability, the Board needs to make a judgment regarding whether a policy or plan of insurance can be developed into an insurance product meeting actuarial and underwriting standards, and that the new product can be implemented into the market by the delivery system. However, because submissions and markets vary, FCIC is reluctant to create set standards or goals that may not be appropriate in all situations. In addition, no matter what standards are created, external expert reviewers, RMA and the Board may still differ because they may be emphasizing one aspect over the other. For example, actuaries may believe the rates are not viable because they do not reflect the risk but underwriters may believe the policy is viable because it can be developed into a product that can provide meaningful coverage to producers. It is the Board's responsibility to consider all comments and use its best judgment. Costs of development and implementation can be a consideration of the potential to develop the concept proposal or submission into a policy or plan of insurance that can be offered for sale to producers. The Board has received numerous submissions and concept proposals where the original cost estimates are substantially less than the amount of research and development reimbursement actually requested. In some cases, actual costs were more than double the original estimates. Excessive costs may be an indication that a concept or submission may not be viable or marketable.

Given the inaccuracy of the estimates received by the Board, FCIC is revising the provisions to require that submitters provide more accurate estimates of costs, and since this is a consideration of viability, reimbursement may be limited to the estimated amount unless the submitter can justify the additional costs.

§ 400.703—Timing and Format

Comment: A commenter stated that the proposed rule in § 400.703(b)(1) requires 508(h) submissions, concept proposals or index-based weather plans of insurance to be provided in electronic format. The electronic format is required to be in a single document. The commenter stated they appreciate the desire for single documents, but FCIC must recognize that some of the requirements it places on submitters and materials that may be submitted to FCIC with a concept paper, 508(h) submission etc., may include PDF files, Excel files, databases and other forms of documentation that do not fit neatly into a requirement for a single document. The commenter states that as written, the requirement for electronic format in § 400.703 will be difficult to impossible to meet. For example, further within this regulation the agency asks for letters demonstrating support. Those letters are likely to be in PDF format and they will not fit neatly inside a Microsoft word document. Additionally, the commenter asked, how a submitter would place an Excel workbook inside a word document if a submitter wishes to include an Excel workbook. While the commenter stated they appreciate the concern FCIC may have with multiple documents, the proposed solution falls short of solving the problem for all parties involved in the submission process. A different solution, such as a zip file with a control document, seems more appropriate.

Response: FCIC agrees with the commenter that the required information may not conveniently fit into a single document. The purpose of this proposed provision is to assure information is in the correct order and easily locatable by the reviewers. Because PDF files can be converted to Microsoft Word files and Excel files can be embedded in a Microsoft word document, FCIC believes it is possible to provide the required information in a single document. However, FCIC agrees it may not always be practical to embed such files in a single document. For example, an Excel file may have more columns than what will easily fit within the margins of a Word document. Therefore, FCIC has revised the provision by removing the requirement that all required information must be included in a single document. FCIC has replaced this requirement with a requirement to provide a document that contains a detailed index that, in sequential order, references the location of the required information that may either be contained within the document or in a separate file. The detailed index must clearly identify each required section and include the page number if the information is contained in the document or file name if the information is contained in a separate file.

Comment: A commenter stated that the requirement to provide two hard copies in § 400.703(b)(2) directly conflicts with the FCIC stated intention of easing the burden on submitters. This requirement increases the burden on submitters to no benefit for the FCIC. Electronic communication should be preferred and the requirement for hard copies should be eliminated from the final rule. By requiring two hard copies from the submitters, submitters must now keep a store of the appropriate materials necessary to submit the hard copies that are required only by FCIC, allow time for the production of hard copies that provide minor benefit to the FCIC, proceed to the post office or mail store to put the hard copies in the mail, incur the risk of not having the hard copies exactly match the electronic copy, etc. Because FCIC very clearly stated in the preamble to the rule that its intention was to ease the burden on submitters, FCIC should recognize requirement for hard copies increases the burden on submitters and the requirement for hard copies should be eliminated from the final rule. The background material for the regulation indicates that the rule was drafted in part to lessen the burden on submitters by reducing the number of printed copies required. However, what the drafters of the regulation have done increases the effort of submitters. The requirement for materials to be submitted in a three ring binder in subsection (a) with page numbers in section dividers is not at all helpful and does not lessen the burden. The requirement substantially increases the paperwork difficulty for submitters and in so doing contradicts the stated objective of reducing the burden on submitters. This will increase the burden for submitters at no foreseeable benefit for the RMA. A single copy of the electronic document is insufficient for review purposes, therefore the FCIC will need additional copies of the 508(h) submission, presumably from the electronic version, for reviewers. So the gain to FCIC appears to be nil, while the burden on submitters increases. FCIC should drop the requirement for a hard copy altogether and accept electronic copies only because FCIC has already proposed a system whereby it agrees to make copies for its review process.

Response: FCIC proposed to reduce the number of hard copies required to be submitted from six down to two. Therefore, FCIC disagrees with the commenter that the proposal to provide two hard copies increases the burden on submitters. However, FCIC recognizes that removing the requirement for a hard copy to be submitted would further reduce the burden. Therefore, FCIC has revised the final rule to eliminate the requirement for the submitter to provide hard copies. Submitters will be required to submit an electronic copy either by email or on a removable storage device (including CD or USB drive) by mail, but not both. FCIC has also provided a single email address and a single postal address to avoid duplicative work by submitters and to prevent confusion for FCIC.

Comment: A commenter referenced § 400.703(g), which states that the Board, or RMA if authorized by the Board, shall determine when sales can begin for a 508(h) submission approved by the Board. The commenter recommends that either RMA be given more authority by the Board or that RMA is always authorized by the Board to make determinations when sales can begin for an approved 508(h) submission. A recent example of the problems created by not taking all of the above into consideration is the Livestock Risk Protection (LRP) program for lambs. The insurance year for LRP Lamb starts on July 1 and ends on June 30 of the following year. The LRP program rules require that agents be trained for three hours annually before they are authorized to write a livestock policy. The AIPs generally plan their livestock training for late May and June in order to have their agents properly trained by the time the insurance period begins on July 1. The LRP lamb program was previously developed and written for several years, but was suspended due to some problems with the program. The developers made significant revisions to the program and RMA recently announced that sales would resume on May 4, 2015. The AIPs already scheduled livestock training sessions for their agents for late May and June in preparation for the beginning of the livestock insurance period, which begins on July 1. The commenter notes that submitters have to hold additional training sessions for those agents who wish to write LRP lambs to assure they are aware of all the revisions made to this program. This could have easily been included with the normal training cycle if program sales would have resumed on July 1 instead of May 4. This is a perfect example of problems that occur with releasing a program and not considering the time cycle of the program along with the administrative issues the release causes to the AIPs who will be administering this program. The ideal release date for the revised LRP lamb program would be July 1, which coincides with the start of the insurance period and allows the AIPs to properly train their agents about the LRP lamb revisions made during the normal scheduled time frame for livestock training sessions. In summary, the commenter stated the Board needs to provide RMA with more authority to make the determinations when sales should begin for an approved 508(h) submission. RMA should take into consideration the time cycle of the approved product and the administrative functions AIPs must complete when making the decision of when sales will begin for the approved 508(h) submission. AIPs who choose to participate in these approved 508(h) submissions are the ones responsible for all administrative tasks involved with writing new programs from agent training, computer programming, form development etc. The decision to determine when sales begin should include the administrative tasks completed by the AIPs and the time cycle of the approved 508(h) submission.

Response: While the comment is relevant to the referenced provision, FCIC does not believe changing the provision to give RMA more authority to determine when a 508(h) submission can be implemented will solve the issues identified by the commenter. The problem is that RMA and the Board may not be aware of the types of issues raised by the commenter and submitters are asking for implementation as quickly as possible. In response to this and other comments, FCIC has revised the rule to require applicants to include a marketability assessment from an AIP supporting the submission and that the AIP be more involved in the submission process. FCIC is also revising the rule to require that at least one other AIP be consulted and provide analysis of potential implementation issues. If a marketability assessment by another AIP is not provided as part of the submission, the applicant must provide information regarding the names of the persons and AIPs contacted and the basis for their refusal to provide the marketability assessment. If the applicant cannot obtain a marketability assessment by another AIP, the Board will presume that the submission is unmarketable and it will be a very heavy burden on the submitter to overcome the presumption. By requiring involvement of at least two AIPs, RMA and the Board can be made aware of implementation and other issues before the issues become problems and take appropriate actions.

§ 400.704—Covered by This Subpart

Comment: A commenter offered support of the provision in § 400.704 that allows an applicant to submit a concept proposal to the Board prior to developing a full 508(h) submission. The commenter believes this will expedite and streamline the process by enabling the applicant to develop a better initial product with feedback from the Board.

Response: FCIC appreciates the comment and the support for concept proposals.

§ 400.705—Contents for New and Changed 508(h) Submissions, Concept Proposals, and Index-Based Weather Plans of Insurance

Comment: A commenter stated that new requirements in § 400.705(a) disallowing appended items or requiring a single software to be used may also result in important information being excluded.

Response: FCIC agrees the requirement for information to be included in single document and disallowing appended items could result in important information being excluded. Therefore, FCIC has removed the provision in § 400.705(a) restricting items from being appended to the end of the document. FCIC has also removed the requirement in § 400.703(b) that requires information to be included in a single document and replaced it with a requirement to provide a document that contains a detailed index that, in sequential order, references the location of the required information that may either be contained within the document or in a separate file.

Comment: A commenter stated they believe the revisions made in § 400.705 are problematic due to the fact that the ability of a concept proposal or complete 508(h) submission to move forward will be reliant on standards that are not easily measured. It will be very difficult for a submitter to know whether a proposal meets RMA and the Board's sole view that the concept proposal or 508(h) submission is both "complete" and of "sufficient quality." The determination leaves a submitter with no opportunity for appeal of the decision if rejected. The commenter recommends FCIC incorporate language that provides submitters clear and measurable standards and a fair appeal process when the Board deems a 508(h) submission fails to meet those standards. The commenter continues to offer that § 400.705 is the heart of the 508(h) submission itself. RMA has been accepting 508(h) submissions for over 10 years. With over a decade of experience, RMA should have a clear notion of sufficient quality for the finite number of requirements contained in this paragraph. The commenter stated they believe this paragraph requires approximately 12 standards for clear communication with submitters. In particular, clear and transparent standards should be provided for § 400.705(d), the policy provisions,

§ 400.705(e), the marketing plan, § 400.705(g), the prices and rates of premium. The three paragraphs require the creation of standards that describe a successful set of Crop Provisions, approximately six standards for the marketing plan and standards for the prices and rates of premium that include standards for acceptable data (although this can be a little dangerous).

Response: FCIC believes the requirements contained in § 400.705 are clear and transparent, but simply providing an item on a list does not mean that the submission is complete. Unfortunately, over the years the Board has experienced a number of submissions that contained all the required items in § 400.705 but the contents were of such poor quality that it cost the Board, RMA and ultimately taxpayer's unnecessary funds to review the submission numerous times before the submission morphed into a level of quality that could be sent to expert review or be considered for approval. For this reason, and the reasons stated above, RMA is revising the definition of "sufficient quality" to make it clear that the submission must contain the data, analysis, and conclusions to support the information provided in the submission. In many instances where the Board concluded the submission or concept proposal was not complete was because it lacked the data or analysis needed for external expert reviewers, RMA and the Board to determine that the information provided was reasonable and would meet the standards necessary for approval. For example, some submissions identified a proxy crop without providing any agronomic or risk information to show that the proxy crop would correlate with the crop to be insured. In some cases, adjustments are made to rates without explaining why such adjustments are necessary and the basis for the amount of the adjustment. In other cases, assumptions are made without stating the basis for the assumptions. In those cases, external expert review would be meaningless because there is not enough information to make any judgments on whether the standards for approval have been met. Instead of a formal appeals process, section 508(h) of the Federal Crop Insurance Act provides a process whereby the Board provides notice of intent to disapprove a 508(h) submission outlining its concerns and reasons, and the submitter has the opportunity to address the Board's concerns with additional information or making changes as needed. In addition, the submitter can request a time delay to address issues raised by the Board.

Comment: A commenter stated that the request in § 400.705(c)(2) is redundant. It is the same request found in § 400.705(e)(4) rephrased. The commenter stated that redundancy is always problematic because it tends to precipitate questions if there is not precise agreement in the responses to the redundant requests. The commenter urges FCIC to list a requirement one time and especially that the RMA not repeat any requirement in the final rule.

Response: FCIC agrees with the commenter that these sections are somewhat redundant. Section 400.705(c)(2) requests similar information to what is required under § 400.705(e). FCIC has revised the final rule by consolidating the requirement in § 400.705(c)(2) under § 400.705(e).

Comment: A commenter states that the requirement in § 400.705(c)(3) seems better placed within § 400.705(e).

Response: FCIC agrees with the commenter that § 400.705(c)(3) would be better placed within § 400.705(e). FCIC has revised the final rule by moving the requirements in § 400.705(c)(3) to section § 400.705(e).

Comment: A commenter stated that the requirement in § 400.705(c)(5) seems better placed in § 400.705(d). Section 400.705(d) contains the Crop Provisions. It seems far more logical to describe the coverage in the section containing the very language creating the coverage, the Crop Provisions.

Response: FCIC disagrees with the commenter. Section 400.705(c) is related to clearly understanding the benefits the plan provides to producers and asks for a summary of such benefits. Section 400.705(c)(5) requests a detailed description of the coverage provided and its applicability to all producers, including targeted producers. Section 400.705(d) contains the actual policy. Although the information requested in § 400.705(c)(5) is relevant to policy referenced in § 400.705(d), it more appropriately resides in § 400.705(c) to allow the Board to assess the benefits provided.

Comment: A commenter stated that the language in § 400.705(d) suggests the 508(h) submission must be clearly written so that the producers are able to understand the coverage being offered and that the policy language permits actuaries to form a clear understanding of payment contingencies. The commenter stated that this is a good and reasonable standard and suggests that RMA apply the same standard to this proposed rule. The commenter states that the proposed rule is too vague for a submitter to form a clear understanding regarding what the FCIC considers sufficient quality. In approximately 12 locations within § 400.705 are 508(h) submission requirements lacking a definition that is either clear or understandable. Worse, the proposed rule resolves the problem by incorporating a statement regarding sufficient quality and then allows that determination to be arbitrary and capricious. And yet, here is a standard imposed on the submitter to be clear.

Response: FCIC understands the commenter's desire for clear standards. In § 400.705, FCIC attempted to clearly state the requirements for 508(h) submissions, as appropriate. Sufficient quality is a measurement of how well the submitters have supported the information provided in the 12 categories. FCIC has attempted to do this by revising the definition of "sufficient quality" to make it clear that all information provided and assertions made in § 400.705 must be supported by data or analysis. Bare assertions without establishing the basis for the assertions are no longer sufficient. This provides a more concrete standard and one submitters should be able to meet. However, because submissions vary so greatly, it is impossible to show standards for sufficiency in each subsection in § 400.705.

Comment: A commenter questioned whether the development of the proposed marketing plan, as required in § 400.705(e), is really in the best interest of taxpayers since it will significantly increase the cost of developing a 508(h) submission. The commenter would understand the need for a marketing plan if there was limited interest in a proposed insurance program. However, this seems to be largely unnecessary if there is an obvious and broad-based demand for the crop insurance program by the potential insureds. If the marketing plan requirement is ultimately included in the final rule, RMA should publish standards that a submitter can follow in order to meet the requirements and for the external expert reviewers to use in evaluating the marketing plan for the proposed program.

Response: As stated above, a "marketing plan" is a misnomer because the name suggests how a product will be marketed to producers. However, the purpose of § 400.705(e) is to provide information regarding the marketability of the policy or other coverage because now this is one of the criteria for approval of concept proposals and submissions. Concept proposals and submissions must be deemed marketable to be approved for reinsurance by the Board. The commenter claims that the marketing plan is unnecessary when there is an obvious and broad-based demand for the product, but history has shown a substantial percentage of submissions where submitters provided letters stating there was great interest and demand for the product but only a very small percentage of producers actually bought the policy or coverage when it was available for sale. Therefore, § 400.705(e) is necessary to provide information to the Board to allow it to better make an assessment of marketability. Further, FCIC has revised the standards to allow a more meaningful assessment by looking at actual indicators of producer interest and marketability, such as the amount of data producers are willing to provide, their participation in the development process, etc. FCIC has made revisions in the final rule to § 400.705(e) in an attempt to clarify the marketability requirements. FCIC believes the standards published in the final rule are clearly defined and achievable.

Comment: A commenter stated that the requirement in § 400.705(e)(3) has two problems. First, the vague term "reasonable estimate" begs the question reasonable to whom. Rather than using vague terms, the commenter suggested FCIC describe reasonable in objective terms. Furthermore, the commenter finds the use of other similar products for comparison purposes likely to lead reviewers down the wrong path. Market acceptance increases with grower involvement and participation in the development process and decreases when growers' confidence in the product is diminished. For example, the fresh market bean insurance program began strong. Most acres were insured at the buy-up level. However, after growers made a request to correct a program feature they considered disadvantageous and the correction was not implemented, grower confidence in the program wavered and sales declined. One would not want to use the fresh market bean product for comparison purposes given that the wound is self-inflicted.

Response: "Reasonable estimate" means in the best judgment of the submitter based on all the information available to the submitter, and provided with the submission. RMA has revised the rule to require that submitters provide the information upon which they judge the reasonableness of the projected participation estimate, including the level of participation of producers in the development of the product, their type of participation, and whether they have provided the available data to assist the submitter in the development of the product. Although "reasonable estimate" is not an objective term, FCIC believes this is an appropriate standard to describe what is expected of the submitter. With respect to the requirement to estimate the market penetration of other similar products, FCIC agrees with the commenter that simply estimating the market penetration of other similar products may not adequately convey expected producer interest and participation. Therefore, FCIC has revised the final rule to require the submitter compare other similar products with the 508(h) submission and identify potential differences between the 508(h) submission and the similar products that might make the participation and level of coverage of the proposed product different.

Comment: A commenter stated that it seems unlikely the requirement in § 400.705(e)(5) provides real value within the 508(h) submission process and § 400.705(e)(5) should not be in the final rule. Given the requirement shown at § 400.705(e)(6), the commenter questioned what the vague requirement at § 400.705(e)(5) can add. In fact, the vagueness of this requirement indicates the drafters of the proposed rule are not entirely clear regarding what this requirement should contain.

Response: FCIC disagrees with the commenter that the focus group results requirement in § 400.705(e)(5) should not be included in the final rule. However, FCIC determined this requirement can be combined under § 400.705(e)(6). Therefore, FCIC deleted § 400.705(e)(5), redesignated the succeeding sections, and added the focus group requirement under the newly redesignated § 400.705(e)(5). FCIC also added provisions that add more detail so the results of focus groups can provide more useful information to the Board so it can be considered one of the tools to assist the Board in determining marketability. Focus group information to be provided will now include the type of coverage producers want and what they are willing to pay, which, with all the other available information, will allow the external expert reviewers, RMA, and the Board to make better judgments on whether the product is viable and marketable.

Comment: A commenter stated they believe it would be helpful for FCIC to describe its concept of a market research study at § 400.705(e)(6). The requirement in § 400.705(e)(6) to show demand and coverage levels for which producers are willing to pay introduces a complex problem for submitters because the standard itself lacks definition. According to the regulation, an estimate that shows demand and the level of coverage for which producers are willing to pay is sufficient to meet the standard. It is unlikely this is the intent. In short, it appears the concept of an acceptable market research study remains fuzzy even to the drafters of the proposed rule.

Response: FCIC has combined the focus group provisions with the market research study to allow submitters to provide data on its efforts to judge market interest in the product. Some policies approved under section 508(h) fail to sell because the coverage provided is not specifically desired by producers and the coverage they desire may not be insurable under the Act, or cannot be properly underwritten. Even when coverage may be available, it may not be available at a price producers are willing to pay. Collection of this information during the research and development process can provide more useful information to judge whether a product is marketable.

Comment: A commenter stated that nothing within the expertise of most submitters qualifies the submitter to estimate cost for organizations whose cost structures are unknown to the submitter as required at § 400.705(e)(8). This requirement appears to be the addition of a requirement that cannot be practically answered. It is possible to answer questions related to training requirements, whether the proposed program is amenable to current data record layouts. However, estimating the impact on 17 or 18 or 20 AIP computer systems, estimating administrative and training costs for 17 or 18 or 20 AIP's and determining whether any efficiency will be gained is not likely to net insightful answers. The commenter concludes that what does seem practical at § 400.705(e)(8) is a discussion of whether the proposed program will place new demands upon the computer system that go beyond existing database structures.

Response: FCIC agrees that it may be impractical to expect submitters to assess expected costs for these items. However, the effect of new products on the delivery system is statutorily mandated and given the limited resources available to RMA and AIPs, it is a serious consideration. For this and the other reasons stated herein, FCIC has revised the rule to require that submitters obtain an assessment from at least one AIP who is involved in the development of the product and that at least one other AIP is consulted. FCIC believes it is useful for the submitting AIP to provide insight not only marketability, but also on computer system impacts, administrative and training requirements, potential efficiencies or effects on workload for AIPs or others participating in the program, and whether the policy or plan of insurance is consistent with the terms of the SRA. Therefore, FCIC added requirements to assess potential effects on the workload for AIPs or others participating in the program and whether the policy or plan of insurance is consistent with the terms of the SRA.

Comment: A commenter stated that the requirement to include correspondence from producers in § 400.705(e)(9) does not appear to provide valuable information. For example, at § 400.705(e)(5) of this proposed rule, the requirement is to provide focus groups results. In addition, at § 400.705(e)(6)(i) of the proposed rule requests evidence the proposed 508(h) submission will be positively received. At the very least, § 400.705(e)(9) requests information that is required in a different form at several other locations within the proposed rule. The commenter suggests that the RMA combine its requests regarding grower interest in the insurance program into a single unified requirement. Furthermore, if the 508(h) submission is from or includes a grower organization, then it appears the spirit of § 400.705(e)(9) is met. Asking for additional correspondence creates redundant effort, § 400.705(e)(9) should be required only in the absence of other means of demonstrating grower interest in the proposal.

Response: FCIC agrees with the commenter that the requirement in § 400.705(e)(9) to include correspondence from producers expressing the need for a policy or plan of insurance may not be as valuable as other information requested in the revised rule. There have been a number of submissions where producers have written letters in support or appeared in person to present the submission, but when the product is made available for sale there are few producers actually buying the product. There are a number of reasons for this, including the final product approved does not contain the coverage actually wanted by producers because of statutory or underwriting limitations or the price for the coverage is too high. Therefore, as stated above, FCIC has revised the information regarding the marketing research to address these and other issues so that the external expert reviewers, RMA and the Board can make more informed decisions on marketability before the submission is approved and before significant time, money and resources are invested in implementation of the product.

Comment: A commenter noted that it appears the information required in § 400.705(f)(1) through (5) should be contained within the underwriting guide. Rather than another redundant request, the commenter suggested FCIC require an underwriting guide with definitions that include and may expand upon items one through five in a manner similar to the information contained in § 400.705(f)(7).

Response: FCIC agrees the contents of § 400.705(f)(1) through (3) should be contained in the underwriting guide. However, the contents of § 400.705(f)(4) and (5) fit more appropriately in the loss adjustment standards handbook. FCIC agrees it is not necessary to have duplicate requirements that can be included in these handbooks. Therefore, FCIC revised the final rule to include the contents of § 400.705(f)(1) through (5) in the requirements for the underwriting guide and the loss adjustment standards handbook, as appropriate.

Comment: A commenter stated that § 400.705(f)(2) "Relevant Dates" is a nonspecific requirement. The commenter stated FCIC should list the dates it considers relevant in the final rule.

Response: FCIC agrees that it may be helpful to include example dates that may be relevant. Therefore, FCIC included in the final rule an example of dates that may be relevant in § 400.705(f).

Comment: A commenter noted that the proposed rule in § 400.705(g)(1) appears to contain a requirement to propose a specific premium rating methodology. If that is the intention of FCIC, the commenter suggests that the word "specific" be deleted from the final rule. As FCIC and expert reviewers have noted, many of the crops remaining to receive the benefits of a crop insurance program will require creative efforts to estimate rates.

Response: FCIC agrees the term "specific" is superfluous. Therefore, FCIC removed the term "specific" from § 400.705(g)(1) in the final rule.

Comment: A commenter noted that the requirement in § 400.705(h) appears to be a redundant requirement. If, for example, the underwriting guide and loss adjustment manual contain forms, and they will, those forms must be separated from the document and placed in § 400.705(h). Completing this section becomes an exercise in cut and paste with dubious relevance in a review process. A reviewer needs to review any form within the context of its use and the form has context within the document that contains the form and its instructions for use. The requirement at § 400.705(h) should be removed from the final rule.

Response: FCIC agrees the requirements in § 400.705(h) are redundant. Therefore, FCIC deleted this section in the final rule and redesignated the succeeding sections.

Comment: A commenter suggested that the clause in § 400.705(i)(1) proposes to restrict open commerce. It seems unlikely this requirement is legal. The statement attempts to undo the long history of using insurance brokers to facilitate the creation of insurance. Insurance brokers are forbidden in crop insurance. The requirement is discriminatory. One who is a submitter is prohibited from marketing that which they developed. The statement attempts to restrict the AIP and its agents from selling the crop insurance they have signed up to support. The commenter questioned how a submitter who is not an AIP will be able to meet the requirement in § 400.705(e)(10) given that this would appear to bar the AIP from sales. The commenter stated the requirement serves no legitimate business purpose other than to discourage development of new insurance products.

Response: The proposed § 400.705(i)(1) requires a statement certifying the submitter and AIP, or its affiliates, will not solicit or market the 508(h) submission until at least 60 days after all policy materials are released to the public by RMA, unless otherwise specified by the Board. The purpose is to create a level playing field so the submitter does not have an unfair marketing or sales advantage. Section 508(h) of the Act states that any submission approved for reinsurance can be sold by any AIP wanting to do so. It would not be fair to other AIPs if the submitter was allowed to start soliciting sooner than the other AIPs. However, FCIC recognizes, as currently written the 60-day delay is not necessary and has generally not been enforced. Rather, it has been FCIC intent and past practice to allow marketing to commence once all policy materials are released to the public. FCIC strives to release policy materials at least 60 days prior to the earliest sales closing date. Therefore, FCIC has revised this provision to state that the submitter must certify that the submitter and any approved insurance provider or its affiliates will not solicit or market the submission until all policy materials are released to the public by RMA, unless otherwise specified by the Board.

Comment: With respect to the requirement in the proposed § 400.705(i)(3), a commenter questioned when agent and loss adjuster training plans are applicable.

Response: Agent and loss adjuster training plans are not applicable to proposed rates of premium for a policy. Therefore, FCIC has revised newly redesignated § 400.705(h)(3) by removing the phrase "if applicable" and specifying agent and loss adjuster training plans must be provided, except for 508(h) submissions only proposing changes to rates of premium for an existing policy.

§ 400.706—Review

Comment: A few commenters expressed concern about the lack of a suitable appeal or review process for submitters who put together packages in good faith, but are then subject to a closed review process dependent on the Board and RMA being given the ability to determine "at its sole discretion" [in § 400.706(a)(3) and elsewhere in the rule] whether or not a proposal is complete or meets the subjective requirements outlined in the proposed rule. The commenters stated the proposed rule fails to give submitters a clear standard by which to judge the quality of a proposal. The commenters are concerned that as written the proposed rule eliminates due process, increases the potential for the intent of the Act to be administered inconsistent with its intent. One commenter stated the clause in § 400.706(a)(3) is hostile toward submitters. Another commenter requested FCIC provide clear, measurable standards in regards to the requirements that submitters must meet, as well as to ensure that the decisions they make are based on the same sound and transparent standards.

Response: The 2014 Farm Bill revised the criteria in the Act for review of submissions and expressly gave RMA the authority to determine whether the policy or plan of insurance will likely result in a viable and marketable policy that will provide crop insurance coverage in a significantly improved form and adequately protect the interests of producers. The provisions contained in the Act cannot be waived by this regulation. Unfortunately, over the years the Board has experienced addressing a number of submissions that were of poor quality that cost the Board, RMA and ultimately taxpayer's unnecessary funds to review numerous times before the submission morphed into a level of quality that could be sent to expert review or be considered for approval. FCIC agrees these standards are necessarily general but given all potential products have not been conceived, it is impossible to set tighter standards. However, FCIC will be reviewing the submitter's detailed description of why the terms have been met. Further, even if RMA were to use its discretion and reject a submission, it does not end the process. It simply means that the submitter must make improvements to the quality or contents of the submission.

Comment: A few commenters raised concerns with § 400.706(b)(2)(i), which indicates that no reviewer can be employed by an approved insurance provider (AIP) or be a representative of an AIP. The commenters stated they understand why a competing AIP should not be a reviewer, but question why an organization like the National Crop Insurance Services (NCIS) should be excluded from a confidential review. This is a review that the NCIS would conduct in a confidential manner without any involvement of their member AIPs. The commenters would recommend that RMA not exclude organizations like the NCIS from a possible review as it could add industry perspective that RMA would not otherwise be able to receive as a part of the expert review process.

Response: FCIC understands the commenter's perspective that an agency that is representative of AIPs could provide valuable reviews. However, the provision is intended to prevent bias that may result if an organization that represents interested stakeholders is involved in reviewing products that may be sold by those stakeholders. This provision was not proposed to be changed in the proposed rule. No change has been made in the final rule. However, in response to other comments, FCIC has increased the required involvement of the AIP in the process by requiring that at least one AIP be part of the submitter and that another AIP provide an assessment of the impacts of the submission on the delivery system and marketability of the submission.

Comment: A commenter stated that the use of the word "appropriate" in § 400.706(b)(2)(ii)(C) leads to subjective determinations. The commenter questioned who determines what is appropriate. The commenter suggested that a better wording would be "follows recognized insurance principles."

Response: FCIC agrees the provision would be better worded if the term "appropriate" was changed to "recognized." FCIC has made this change in § 400.706(b)(2)(ii)(C) of the final rule.

Comment: A commenter asked what an "excessive risk" is, in reference to § 400.706(b)(2)(ii)(E).

Response: FCIC has clarified in the final rule that excessive risk includes, but is not limited to, risk that encourages adverse selection, moral hazard, or risks that cannot be properly rated. Examples of excessive risk might be proposing to insure commodities in an area where the commodity is not generally recognized as a suitable growing environment or in an area likely to be frequently adversely affected by a known peril.

Comment: A commenter stated that, including § 400.706(b)(2)(ii)(I), the term "new kind of coverage" appears in several locations throughout the proposed rule. The term is not entirely clear. For example, in the clause above new kind of coverage applies to a crop that previously had no available crop insurance, but it also applies to crops with low participation or that are insured at a low coverage level. Attempts to remedy low participation or low coverage levels may not involve "a new kind of coverage." It is conceivable, and even likely, that efforts to improve participation may simply involve redesigned coverage, but not necessarily anything "new." Certainly in the case of crops with low participation concerns, the term "new kind of coverage" could easily become problematic. The commenter suggests the RMA either define the term or reconsider its use for crops with existing insurance programs where low participation levels are a concern.

Response: FCIC agrees with the commenter that the provision in § 400.706(b)(2)(ii)(I) could be problematic if the phrase "new kind of coverage" applies to the second part of the sentence in § 400.706(b)(2)(ii)(I). FCIC has revised the provision by removing the term "new kind of coverage" and replacing it with the phrase "new or improved coverage." This change clarifies that a policy or plan of insurance could fall under the context of this provision if it provides improved coverage that addresses low participation or high levels of participation at low coverage levels.

Comment: A commenter stated no marketing plan can demonstrate an insurance product is marketable as required in § 400.706(b)(2)(ii)(K). Marketability comes from the ability of the insurance instrument to adequately cover risk at a price growers will be willing to pay. The commenter stated the marketing plan is simply "the delivery system will sell and service the insurance plan." The commenter asserts that within hours of the announcement of a new program, agents respond by chasing the new commission money. The commenter believes the real challenge is to give the agent something to sell.

Response: As stated above, FCIC has removed the concept of a marketing plan and replaced it with a marketability assessment of the policy or plan of insurance. Further, those provisions now will require submitters to provide additional indicators of marketability, such as producer interest as measured by their willingness to assist and provide the data necessary in the development process, whether the submission can provide the coverage desired by producers at a price producers are willing to pay, AIPs assessment of the ability to sell the product, etc. FCIC believes that looking at these additional factors will allow the Board to make better judgments in approving policies and plans of insurance agents can sell.

Comment: A commenter stated that it is not entirely clear from the regulation if the proposed requirement in § 400.706(b)(2)(ii)(K) to have a comprehensive "marketing plan" submitted is with the concept proposal or with the complete 508(h) submission. If it is with the concept proposal, this requirement is premature given that the policy has not been fully developed nor have the premium rates been established. The purpose of the concept proposal is to have a proof of concept approved prior to the majority of the investment of time and resources into developing a complete 508(h) submission. For the marketing plan to be complete for the concept proposal, it would essentially have to have been developed prior to the concept being approved, which is obviously in contradiction to the purpose of the concept proposal.

Response: Marketability is a consideration in both the concept proposal and submission stages. However, FCIC recognizes that more information will be available at the submission stage and scrutiny by the Board will be higher. Therefore, while the Board will consider marketability at both stages, requirements may differ. Those requirements and standards relating to concept proposals are contained in Procedures Handbook 17030—Approved Procedures for Submission of Concept Proposals Seeking Advance Payment of Research and Development Cost. While the definition of submission excludes concept proposals, FCIC recognizes that the term "submission" is also commonly used when referring to concept proposals. Therefore, FCIC has changed the definition and all references of "submission" to "508(h) submission." This change is expected to help eliminate potential confusion by providing a clearer distinction between 508(h) submissions and concept proposals in this regulation.

Comment: A commenter stated that the proposed rule in § 400.706(b)(5) establishes the unabashedly arbitrary rule. No standard applies. What seems most unsettling about this rule is the three items the rule applies to, lend themselves to an objective decision.

Response: FCIC determined the provision in § 400.706(b)(5) is out of place and is not needed because subsequent provisions describe the process for approval and disapproval. Therefore, to prevent confusion the provision in § 400.706(b)(5) relating to 508(h) submissions, and similar provisions in § 400.706(c)(9) and (d)(5) referencing concept proposals and index-based weather plans have been deleted in the final rule.

Comment: A commenter stated it is important to note that while the law allows the Board to prioritize the approval of policies or plans of insurance as described in § 400.706(g), the exercise of this authority must be performed in an open and transparent manner. Doing so is vital to the ongoing success of the 508(h) process and is necessary to avoid the perception that the 508(h) process is not being implemented in a manner as intended by Congress. Further, it is the commenter's belief that any products related to cotton should be included under the second priority of "existing policies or plans of insurance for which there is inadequate coverage or there exists low levels of participation." While there are products available to cotton producers including STAX as well as yield and revenue policies; these products are the sole risk management tool for cotton producers. In 2014, 30 percent of cotton acres bought coverage at the 60 percent buy-up level or below—17 percent of acres either had no coverage or coverage at the lowest levels available. Any enhancements to these products or the addition of new products or endorsements would be a benefit for cotton growers.

Response: FCIC understands the concern of the submitter that provisions of the Act should be implemented in a transparent manner. However, the Act contains confidentiality standards that prevent FCIC from disclosing information about products that are under consideration for approval, which limits the transparency of the process. However, the Board is considering implementing procedures that will make the process more transparent. In the meantime, to assist the Board in determining if certain commodities such as cotton meet the provision in § 400.706(g)(2), for each policy or plan of insurance submitted for approval, RMA will research and present to the Board information on whether there are existing policies for that commodity and the level of coverage and participation.

Comment: With regard to § 400.706(k)(1), a commenter stated that because protecting the interests of agricultural producers is a review criterion, the Board, RMA, developers and external expert reviewers must share a common understanding of the standard for judging whether a 508(h) submission protects the interests of agricultural producers and taxpayers. This proposed rule does not provide such a standard. The commenter requested that FCIC clarify the meaning of protecting the interests of agricultural producers and taxpayers so that developers can provide America's farmers with 508(h) submissions of sufficient quality.

Response: FCIC disagrees with the commenter that provisions in § 400.706(k)(1) do not provide clear standards for what it means to protect the interests of producers and taxpayers. Because it is not possible to list every scenario that may not protect the interests of producers and taxpayers, the provision includes a list of activities that meet this criteria that is not all-inclusive. This list includes: The 508(h) submission does not provide adequate coverage or treats producers disparately; the applicant has not presented sufficient documentation that the 508(h) submission will provide a new kind of coverage likely to be viable and marketable; coverage would be similar to another policy or plan of insurance that has not demonstrated a low level of participation or does not contain a clear and identifiable flaw and the producer would not significantly benefit from the 508(h) submission; the 508(h) submission may create adverse market distortions or adversely impact other crops or agricultural commodities if marketed; the 508(h) submission will have a significant adverse impact on the private delivery system; or the 508(h) submission cannot be implemented, administered, and delivered effectively and efficiently using RMA's information technology and delivery systems. To address the commenters concern, FCIC included two additional items to describe what protecting producer and taxpayer interests mean. These include ensuring the 508(h) submission does not contain flaws that may encourage adverse selection, moral hazard, or vulnerabilities that allow indemnities to exceed the value of the crop.

§ 400.708—Post Approval

Comment: A commenter stated that § 400.708(a)(1)(ii) indicates that after the 508(h) submission has been approved, a reinsurance agreement must be executed if the terms and conditions differ from the available existing reinsurance agreements. If a separate reinsurance agreement needs to be developed this now creates a situation in which the person or organization who has submitted the product, is more than likely not an existing AIP, but will now be charged with establishing the reinsurance terms for all other AIPs who choose to participate in writing the approved 508(h) submission. This is a major flaw in this regulation as all AIPs who choose to participate in writing this approved 508(h) submission should be involved in the discussions establishing the reinsurance terms for such product or program. This would result in a reinsurance agreement that is more equitable to all parties involved and likely enhance the chances of the new product being successful in the marketplace. The AIPs who must administer and bear the risk of the new product or program need to be involved in the development of the new reinsurance agreement and this regulation should be revised to take this into consideration. An example of this is the flawed Livestock Price Reinsurance Agreement (LPRA) which was developed in accordance with this regulation. The structure of the LPRA provides the AIPs with very little incentive to actively pursue and write livestock policies as it is currently structured. This subsequently results in limited sales and reduces the potential success of the livestock program.

Response: FCIC agrees the terms of the reinsurance agreement developed in accordance with this provision should be established in an equitable manner that takes into consideration the interests of all participating AIPs. However, it is not possible to involve all AIPs that will sell the product, because it is not known which AIPs will choose to sell the product and confidentiality rights of the submitter must be respected. However, if a new or different reinsurance agreement is needed for a newly developed product, FCIC will endure to establish the standard terms of such reinsurance agreement so that they apply equitably to all AIPs, and that no one AIP (including any AIP who is part of the product submission) has a marketing or financial advantage over another AIP. FCIC has revised the final rule to clarify that participating AIPs interests will be considered when the terms of the reinsurance agreement are established.

§ 400.712—Research and Development Reimbursement, Maintenance Reimbursement, Advance Payments for Concept Proposals, and User Fees

Comment: A commenter expressed support of the provision in § 400.712(c) that allows an advance payment of up to 50 percent of the projected total research and develop costs and the new provision which would allow the Board to provide up to an additional 25 percent advance payment. The commenter stated research and development costs of a major plan of insurance can be substantial, with many organizations unable to cover these up-front costs. The additional 25 percent advance payment could be instrumental in these situations, and the commenter encouraged FCIC to proactively use this authority to advance the ability of the RMA to provide growers with sound risk management options.

Response: FCIC appreciates the commenter's support of this provision.

Comment: A commenter stated that § 400.712(c)(1)(ii) is government sanctioned usury. The proposed rule attempts to collect interest at 18 percent per annum for submitters attempting to help American farmers achieve risk management goals. The commenter concludes that this is a shameful proposal.

Response: FCIC disagrees that § 400.712(c)(1)(ii) attempts to collect interest at 18 percent per annum. The provision requires interest to be charged at a rate of 1.25 percent simple interest per calendar month, which results in an annual rate of 15 percent. Furthermore, the referenced provisions are intended to protect taxpayer dollars if developers accept funding from FCIC, but then fail to deliver an acceptable product. Failure to collect interest on the funds provided for development would be fiscally irresponsible. This interest rate was previously included in 17030—Approved Procedures for Submission of Concept Proposals Seeking Advance Payment of Research and Development Expenses. This interest rate is also consistent with the rate charged in section 24(a) of the Common Crop Insurance Policy Basic Provisions for amounts owed to FCIC and in the Standard Reinsurance Agreement. No change has been made in the final rule.

Comment: A few commenters expressed concerns with the reduction in research and development costs contained in § 400.712(e) based on the plan of insurance, complexity of the policy and rates of premium. A common concern was that the proposed reductions in reimbursement for research and development will make it difficult for farm organizations to obtain the services of qualified individuals who can meet the complicated requirements of § 400.705. Another concern that was raised was that if agricultural organizations obtain the services of a developer who does not understand the requirements of this section, the agricultural organization may be required to make up the difference due to reimbursement reductions. Commenters were concerned the criteria used to gauge the level of program complexity may not always be representative of the actual challenges in developing a crop insurance program. Commenters were also concerned that the reductions will come as a surprise to submitters after they have already completed the work. Another concern was that the reductions are based on arbitrary standards. Several commenters recommended the provision be excluded from the final rule.

Response: FCIC understands the concerns of grower groups that may contract with other companies to develop insurance products under the 508(h) process. However, FCIC is statutorily required to consider complexity when making payments, and FCIC is striving to do that in a fair and equitable manner. This means that all submitters must be treated the same regardless of their experience. This rule requires that certain tasks be performed and those tasks are the same for all submitters. However, some of the tasks are simplified because the submitter uses existing policy materials, handbooks, procedures, or rating methodologies so that the hours required to perform the tasks are reduced. The Board takes this reduction into consideration. Therefore, FCIC has revised § 400.712(e) by eliminating the reduction percentages and giving the Board discretion to reduce reimbursement for research and development costs and maintenance costs, as necessary, when requested reimbursement is not commensurate with the complexity or the size of the area proposed to be covered.

Comment: A commenter stated that the proposed rule in § 400.712(i) speaks to the problem submitters will have with this proposed rule. A 508(h) submission may be determined to be of insufficient quality to refer to expert reviewers and the costs associated with perfecting the 508(h) submission may not be considered reimbursable. This may not be a disagreeable rule provided submitters have a clear target. If a submitter knows what the standard is for sufficient quality, fails to meet the standard for sufficient quality then it may be reasonable for the Board to avoid payment for perfecting the 508(h) submission. However, with the standard that is almost completely arbitrary, this rule holds out the possibility of treating submitters disparately. Since the 508(h) process can be considered an invitation to perform work on behalf of the American farmer, FCIC should produce a clear and helpful rule. A substantial number of farmers rely upon the actions of the Board and RMA. Should they choose to become submitters, they deserve clear targets.

Response: The provision in 712(i) is intended to prevent FCIC from paying for the same activities numerous times before a submission is ready for review or consideration of approval due to insufficient quality to conduct a meaningful review, or for errors, omissions and incomplete materials preventing an independent third party from being able to fully read, comprehend and understand the components of a submission. FCIC has clarified provisions regarding sufficient quality to require that the submission include all data, analysis and justification for assumptions made and in support of the information provided in the submission. This is crucial for the conduct of a meaningful external expert review. Therefore, the standard is not arbitrary and can be met by submitters. For example, if the submitter uses a proxy crop, the submitter must include the data and analysis that shows why the proxy was selected, why a proxy is needed, why the proxy selected best correlates with the crop to be insured under the submission, etc. The same applies with premium rating. The submitter must explain all assumptions made and all adjustments. Simply stating math formulas or a complete listing of all types of methodologies is no longer sufficient.

§ 400.713—Non-Reinsured Supplemental (NRS) Policy

Comment: A commenter stated that language was added to § 400.713(a) requiring submission of any non-reinsured supplemental (NRS) policy that covers the same agricultural commodity as any policy reinsured by FCIC under the Federal Crop Insurance Act. The commenter questioned whether the changes now require Crop-Hail policies to be approved by RMA. The commenter stated the regulation should specifically state that Crop-Hail policies are excluded from these rules.

Response: The definition of ''non-reinsured supplemental'' contained in § 400.701 specifically excludes Crop Hail policies. Therefore, it is not necessary to state in § 400.713 that Crop-Hail policies are excluded. No change has been made in the final rule.

Comment: A commenter stated that the proposed rule in § 400.713(a) and (c) says that failure to provide such NRS policy or endorsement to RMA prior to its issuance shall result in the denial of reinsurance, A&O subsidy and risk subsidy on the underlying FCIC reinsured policy for which such NRS policy was sold. Because FCIC prohibits the tying of FCIC reinsured policies and private policies, the AIP that sold the FCIC reinsured policy may not be the AIP that sold the NRS policy. The commenter asked how this language will apply in these cases. The commenter adds that the regulation should exclude penalties from applying to the AIP that sold the underlying FCIC reinsured policy if the NRS is sold by a different AIP.

Response: FCIC agrees with the commenter that the regulation should exclude penalties from applying to AIPs that sold the FCIC reinsured policy if the NRS is sold by a different AIP. However, FCIC does not believe AIPs that sell an NRS policy that is not submitted in accordance with § 400.713 of this regulation or that is found to meet the conditions of § 400.713(c)(1) through (5), should be excluded from penalty. FCIC has revised § 400.713(a) and (c) by removing the penalty for denying reinsurance, A&O subsidy, and risk subsidy on the underlying FCIC reinsured policy if the AIP selling such underlying FCIC reinsured policy is not the company that sold the NRS. FCIC has added in its place a provision that makes the AIP that sold the NRS liable for an amount equal to the reinsurance, A&O subsidy, and risk subsidy on any underlying FCIC policies sold by other AIPs to which the NRS is attached.

Comment: A commenter stated § 400.713(a) states that any NRS policy that is issued before it is approved by RMA will result in a denial or reinsurance on the underlying FCIC reinsurance policy. The denial of reinsurance set-forth in paragraph (a) makes sense. However, in paragraph (c), which sets forth the approval process that RMA will go through 150 days prior to the sales closing date for any NRS policy, RMA states that reinsurance will also be denied on any FCIC reinsured policy not a meeting the prior approval criteria set forth in paragraphs (c)(1) through (5). Since it appears that RMA must approve NRS policies before they are sold, the commenter stated they do not understand the purpose of including a denial of reinsurance penalty in paragraph (c). The commenter suggested that the denial of reinsurance language in paragraph (c) be deleted and that the denial of reinsurance language in paragraph (a) be revised to read as follows: Reinsurance, A&O subsidy and risk subsidy on the underlying FCIC policy will be denied for any NRS policy issued without the prior approval of FCIC under this section.

Response: RMA does not approve NRS policies, rather RMA reviews the policy to determine if the conditions in § 400.713(c)(1) through (5) exist. Therefore, FCIC does not intend to add the suggested ''approval'' language. The provision in § 400.713(a) requires the NRS to be submitted, and if not submitted, provides consequences for not being submitted. The provision in § 400.713(c) requires FCIC to notify the submitter of the consequences if the NRS meets the conditions contained in § 400.713(c)(1) through (5). Therefore, both paragraphs are necessary because they contain different requirements. However, in response to a previous comment, FCIC has revised § 400.713(c)(1) to state that FCIC will notify the AIP that submitted the NRS policy that if they sell the NRS policy, it will result in denial of reinsurance, A&O subsidy, and risk subsidy on all underlying FCIC reinsured policies, unless the underlying FCIC policy was sold by another AIP. If the underlying FCIC reinsured policy is sold by another AIP, the AIP that sold the NRS may be required to pay FCIC an amount equal to the reinsurance, A&O subsidy, and risk subsidy on the underlying FCIC policy.

Comment: A commenter stated that the proposed rule indicates in § 400.713(b) that the NRS policy and related materials must be submitted at least 150 days prior to the first sales closing date applicable to the NRS policy, which is 30 days more lead time than what is currently required. Since the AIPs are being required to submit the NRS policy 30 days earlier, it would also be beneficial for the AIPs if the RMA also responded back to the AIP 90 days before the first sales closing date rather than 60 days as currently required. This would allow additional time to train the agents and to market the NRS product prior to the applicable sales closing date. The commenter recommended that § 400.713(d) of this regulation be changed to require that the RMA will respond back to the AIP not less than 90 days before the first sales closing date rather than 60 days as currently indicated.

Response: FCIC understands the commenter's desire for additional time to train agents and market the product. To give both the AIP and RMA additional time, FCIC has revised § 400.713(d) in the final rule to require RMA to respond 75 days before the first sales closing date, or provide notice why RMA is unable to respond within the time frame allotted. This change gives both FCIC and the AIP an additional 15 days from what was allotted under the previous rule.

Comment: A commenter stated that § 400.713(b)(1) and (2) indicate that three hard copies and an electronic copy of the NRS policy must be sent to the Deputy Administrator for Product Management. If an electronic copy is sent, the commenter does not see the need or value in also sending three hard copies of the same material via regular postal mail. The commenter recommends that the regulation be clarified to indicate that either three hard copies or an electronic copy of the NRS policy be sent, but that both methods of submitting the NRS are not required.

Response: FCIC agrees with the commenter that both an electronic and a hard copy are not necessary. FCIC removed the hard copy requirement from the final rule.

Comment: A few commenters questioned the use of the term "moral hazard" in § 400.713(c)(1)(i). One commenter stated the term moral hazard was added with an example, but it is not a defined term. The commenter asked what constitutes a moral hazard and if moral hazard is applied on a product basis or on an individual insured behavior basis. The commenter asks for clarification on whether FCIC will determine a policy creates a moral hazard based on its performance over a period of time or based on a single instance of abuse. Another commenter suggested defining moral hazard as "the tendency for an insured party to take less care to avoid an insured loss than the party would have taken if the loss had not been insured, or even to act intentionally to bring about that loss."

Response: FCIC disagrees that the term "moral hazard" should be defined in the context of this provision. The term is commonly used in the insurance industry and because the term is not defined it takes on the common meaning. A moral hazard could be on an individual or product basis. FCIC may consider a policy to create a moral hazard if provisions lend themselves to abuse or if data collected shows the performance of the product over time creates an incentive for abuse. No change has been made in the final rule.

Comment: A commenter stated the phrase "aggregate indemnities" was added to § 400.713(c)(1)(i), but does not include a definition. The commenter asks, what is included in determining aggregate indemnities. The commenter adds that the regulation needs to specifically exclude hail insurance indemnities from the aggregate indemnities definition and to define what is included. A commenter also stated that the phrase "expected value" of the insured commodity was added to § 400.713(c)(1)(i). The commenter asks what the definition is of expected value and when the expected value is determined. The commenter stated the regulation needs to define expected value, including what information can be used to determine the expected value and what the time frame is around when the expected value is determined.

Response: FCIC agrees the provision should be revised to clarify what is included in the determination of aggregate indemnities. Hail policies and other policies not reinsured by FCIC would not be included. FCIC also agrees that the concept of expected value needs to be expanded upon in the final rule. FCIC intentionally did not include parameters for determining expected value because this can be defined differently by the submitter. However, the expected value must be based on parameters that represent the value a producer could reasonably expect to receive for the insured commodity. Therefore, FCIC has revised the provision in the final rule by removing the term "aggregate" and adding language stating that a policy will be considered to shift or increase risk if it: (1) Results in the underlying FCIC policy either triggering a loss sooner, or paying a larger indemnity than would otherwise be allowed by the terms and conditions of the underlying reinsured policy; or (2) allows for combined indemnities between the underlying FCIC reinsured policy and the NRS that are in excess of the value a producer would reasonably expect to receive for the insured commodity if a normal crop was produced and sold at a reasonable market price.

Comment: A commenter stated § 400.713(c)(2) can be better and more equitably phrased as follows: "The NRS reduces or limits the rights of the insured with respect to the underlying policy or plan of insurance reinsured by FCIC. An NRS policy will be considered to reduce or limit the rights of the insured with respect to the underlying policy or plan of insurance if it materially affects the terms or conditions of the underlying policy or otherwise materially undermines procedures issued by FCIC."

Response: FCIC agrees with the commenter that including the terms "affects" and "undermines" help to describe when an NRS reduces or limits the rights of the insured. However, FCIC disagrees the phrasing proposed by the commenter to include the term "materially" is appropriate because this would allow for a determination of a degree of significance. FCIC maintains that if an NRS affects, alters, preempts, or undermines the terms or conditions of the underlying policy to any degree, such NRS policy is reducing or limiting the rights of the insured with respect to the underlying policy or plan of insurance. Therefore, FCIC revised the final rule by: Including the terms "affects" and "undermines"; the terms "alters" and "preempts" has been retained; and the term "materially" has not been included.

Comment: A commenter stated that § 400.713(c)(3) may be improved and more equitably phrased by adding the term "materially" prior to the phrase "in excess of normal market demand."

Response: FCIC disagrees that including the term "materially" prior to the phrase "in excess of market demand" is appropriate. FCIC considers an NRS that encourages planting more acres of the insured commodity in excess of normal market demand to disrupt the marketplace, regardless of extent or degree. No change has been made in the final rule.

Comment: A commenter stated that an example of disruption in the marketplace was added in § 400.713(c)(3). The commenter asked what the basis will be for the evaluation. The commenter also asked if this will this be applied on an individual insured basis or a program basis and how much more than normal will be deemed to be excessive. The commenter questioned if the evaluation of excessive will be based on a single year or a certain number of years. A spike in planting may be attributable to factors other than the NRS policy.

Response: The determination will be based on the evaluation of the policy language and any available evidence that substantiates or verifies the NRS will or has disrupted the marketplace. This determination may be applied on an individual or collective basis. If the NRS encourages planting of more acres of the insured commodity in excess of market demand it will be considered to disrupt the marketplace and may be assessed based on a single year or multiple years. FCIC agrees that an increase in planting could be due to factors other than the NRS policy, so RMA will consider all other potential factors before concluding the NRS is the cause of the disruption in the marketplace. FCIC has added the phrase "RMA determines" in § 400.713(c)(1) through (4) to indicate the decision is based on RMA's determination.

Comment: A commenter stated that language was added to the proposed rule in § 400.713(e) requiring a review if the NRS policy exceeds a 2.0 loss ratio. The commenter questions what are the parameters of the 2.0 (*e.g.,* a one year loss ratio, a rolling 3–5 year loss ratio, etc.). The commenter stated the current year loss ratio will be unknown when the required 150 days prior to sales closing date is applied. A gap year must be included in evaluation of loss ratio. The commenter asked if RMA will approve private product rating methodology and/or rates. The commenter also questioned if state department of insurance approval of the rate methodology and/or rates will be superseded by RMA's rejection of the same. The commenter stated that states regulate and approve private product rates. If a state approves the rates associated with a private product, the commenter questioned whether FCIC has the authority under the McCarran-Ferguson Act to reject or dispute those rates.

Response: RMA will not review the premium rates of an NRS policy. Rather, FCIC was proposing to use the loss ratio as a possible indication there could be an underlying issue that may result in risk being shifted to the underlying FCIC reinsured policy. However, FCIC agrees with the commenter that a one year loss ratio would not be sufficient to determine if there was an underlying issue and FCIC already requires a NRS policy to be submitted for review in accordance with § 400.713(c)(1) through (5). FCIC also agrees the AIP may not know the loss ratio 150 days prior to the sales closing date. Because these issues were not addressed in the proposed rule, FCIC has not included this provision in the final rule.

Executive Orders 12866 and 13563

Executive Order 12866, "Regulatory Planning and Review," and Executive Order 13563, "Improving Regulation and Regulatory Review," direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasized the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

The Office of Management and Budget (OMB) designated this rule as not significant under Executive Order 12866, "Regulatory Planning and Review," and therefore, OMB has not reviewed this rule.

Paperwork Reduction Act of 1995

Pursuant to the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the collections of information in this rule have been approved by the Office of Management and Budget (OMB) under control number 0563–0064.

E-Government Act Compliance

FCIC is committed to complying with the E-Government Act of 2002, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA, Pub. L. 104–4) requires Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments, or the private sector. Agencies generally need to prepare a written statement, including a cost-benefit analysis, for proposed and final rules with Federal mandates that may result in expenditures of $100 million or more in any year for State, local, or Tribal governments, in the aggregate, or to the private sector. UMRA generally requires agencies to consider alternatives and adopt the more cost effective or least burdensome alternative that achieves the objectives of the rule. This rule contains no Federal mandates, as defined in Title II of UMRA, for State, local, and Tribal governments or the private sector. Therefore, this rule is not subject to the requirements of sections 202 and 205 of UMRA.

Executive Order 13132

It has been determined under section 1(a) of Executive Order 13132, Federalism, that this rule does not have sufficient implications to warrant consultation with the States. The provisions contained in this rule will not have a substantial direct effect on States, or on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, except as required by law.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, "Consultation and Coordination with Indian Tribal Governments." Executive Order 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes or on the distribution of power and responsibilities between the Federal Government and Indian tribes. FCIC has assessed the impact of this rule on Indian tribes and determined that this rule does not, to our knowledge, have tribal implications that require tribal consultation under Executive Order 13175. If a Tribe requests consultation, FCIC will work with the USDA Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions, and modifications identified in this rule are not expressly mandated by law.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601–612), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA, Pub. L. 104–121), generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to the notice and comment rulemaking requirements under the Administrative Procedure Act or any other law, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. FCIC certifies that this regulation will not have a significant economic impact on a substantial number of small entities. The regulation does not require any more action on the part of the small entities than is required on the part of large entities. No matter the size of the submitter, all submitters are required to perform the same tasks and those tasks are necessary to ensure that the concept proposal can be made into a viable and marketable 508(h) submission and any 508(h) submission can be made into viable and marketable, actuarially sound insurance product. A Regulatory Flexibility Analysis has not been prepared since this regulation does not have an impact on small entities, and, therefore, this regulation is exempt from the provisions of the Regulatory Flexibility Act.

Federal Assistance Program

This program is listed in the Catalog of Federal Domestic Assistance under No. 10.450.

Executive Order 12372

This program is not subject to the provisions of Executive Order 12372, which require intergovernmental consultation with State and local officials. See the Notice related to 7 CFR part 3015, subpart V, published at 48 FR 29115, June 24, 1983.

Executive Order 12988

This rule has been reviewed in accordance with Executive Order 12988 on civil justice reform. The provisions of this rule will not have a retroactive effect. The provisions of this rule will preempt State and local laws to the extent such State and local laws are inconsistent herewith. With respect to any direct action taken by FCIC or to require the insurance provider to take specific action under the terms of the crop insurance policy, the administrative appeal provisions published at 7 CFR part 11 must be exhausted before any action against FCIC for judicial review may be brought.

Environmental Evaluation

This action is not expected to have a significant economic impact on the quality of the human environment, health, or safety. Therefore, neither an Environmental Assessment nor an Environmental Impact Statement is needed.

List of Subjects in 7 CFR Part 400

Administrative practice and procedure, Crop insurance.

Final Rule

Accordingly, as set forth in the preamble, FCIC amends 7 CFR part 400 as follows:

PART 400—GENERAL ADMINISTRATIVE REGULATIONS

■ 1. Revise subpart V to read as follows:

Subpart V—Submission of Policies, Provisions of Policies, Rates of Premium, and Non-Reinsured Supplemental Policies

Sec.

400.700 Basis, purpose, and applicability.
400.701 Definitions.
400.702 Confidentiality and duration of confidentiality.
400.703 Timing and format.
400.704 Covered by this subpart.
400.705 Contents for new and changed 508(h) submissions, concept proposals, and index-based weather plans of insurance.
400.706 Review.
400.707 Presentation to the Board for approval or disapproval.
400.708 Post approval.
400.709 Roles and responsibilities.
400.710 Preemption and premium taxation.
400.711 Right of review, modification, and the withdrawal of approval.
400.712 Research and development reimbursement, maintenance reimbursement, advance payments for concept proposals, and user fees.
400.713 Non-reinsured supplemental (NRS) policy.

Authority: 7 U.S.C. 1506(l), 1506(o), 1508(h), 1522(b), 1523(i).

Subpart V—Submission of Policies, Provisions of Policies, Rates of Premium, and Non-Reinsured Supplemental Policies

§ 400.700 Basis, purpose, and applicability.

This subpart establishes guidelines, the approval process, and responsibilities of FCIC and the applicant for policies, provisions of policies, and rates of premium submitted to the Board as authorized under section 508(h) of the Act. It also provides procedures for reimbursement of research and development costs and maintenance costs for concept proposals and approved 508(h) submissions. Guidelines for submitting concept proposals and the standards for approval and advance payments are provided in this subpart. This subpart also provides guidelines and reference to procedures for submitting index-based weather plans of insurance as authorized under section 523(i) of the Act. The procedures for submitting non-reinsured supplemental policies in accordance with the Standard Reinsurance Agreement (SRA) are also contained within.

§ 400.701 Definitions.

508(h) submission. A policy, plan of insurance, provision of a policy or plan of insurance, or rates of premium provided by an applicant to FCIC in accordance with the requirements of § 400.705.508(h) submissions as referenced in this subpart do not include concept proposals, index-based weather plans of insurance, or non-reinsured supplemental policies.

Act. Subtitle A of the Federal Crop Insurance Act, as amended (7 U.S.C. 1501–1524).

Actuarial documents. The information for the crop or insurance year that is available for public inspection in an agent's office and published on RMA's Web site, and that shows available insurance policies, coverage levels, information needed to determine amounts of insurance and guarantees, prices, premium rates, premium adjustment percentages, practices, particular types or varieties of the insurable crop or agricultural commodity, insurable acreage, and other related information regarding insurance in the county or state.

Actuarially appropriate. A term used to describe premium rates when such rates are expected to cover anticipated losses and establish a reasonable reserve based on valid reasoning, an examination of available risk data, or knowledge or experience of the expected value of future costs associated with the risk to be covered. This will be expressed by a combination of data including, but not limited to liability, premium, indemnity, and loss ratios based on actual data or simulations reflecting the risks covered by the policy.

Administrative and operating (A&O) subsidy. The subsidy for the administrative and operating expenses authorized by the Act and paid by FCIC on behalf of the producer to the approved insurance provider. Loss adjustment expense reimbursement paid by FCIC for catastrophic risk protection (CAT) eligible crop insurance contracts is not considered as A&O subsidy.

Advance payment. A portion, up to 50 percent, of the estimated research and development costs, that may be approved by the Board under section 522(b) of the Act for an approved concept proposal. Upon request of the submitter the Board may at its sole discretion provide up to an additional 25 percent advance payment of the estimated research and development costs after the applicant begins research and development activities if:

(1) The concept proposal will provide coverage for a region or crop that is underserved, including specialty crops; and

(2) The submitter is making satisfactory progress towards developing a viable and marketable 508(h) submission.

Agent. An individual licensed by the State in which an eligible crop insurance contract is sold and serviced for the reinsurance year, and who is employed by, or under contract with, the approved insurance provider, or its designee, to sell and service such eligible crop insurance contracts.

Applicant. Any person or entity that submits to the Board for approval a 508(h) submission under section 508(h) of the Act, a concept proposal under section 522 of the Act, or an index-based weather plan of insurance under section 523(i) of the Act, who must include the AIP that has committed to be involved in the development and submission process and to market, sell and service the policy or plan of insurance.

Approved insurance provider (AIP). A legal entity, including the Company, which has entered into a reinsurance agreement with FCIC for the applicable reinsurance year.

Approved procedures. The applicable handbooks, manuals, memoranda, bulletins or other directives issued by RMA or the Board.

Board. The Board of Directors of FCIC.

Commodity. Has the same meaning as section 518 of the Act.

Complete. A 508(h) submission, concept proposal, or index-based weather plan of insurance determined by RMA and the Board to contain all required documentation in accordance with § 400.705 and is of sufficient quality.

Complexity. Consideration of factors such as originality of policy materials, underwriting methods, actuarial rating methodology, and the pricing methodology used in design, construction and all other steps required for the full development of a policy or plan of insurance.

Concept proposal. A written proposal for a prospective 508(h) submission, submitted under section 522(b) of the Act for advance payment of research and development costs, and containing all the information required in this regulation and the Procedures Handbook 17030—Approved Procedures for Submission of Concept Proposals Seeking Advance Payment of Research and Development Costs, which can be found on the RMA Web site at *www.rma.usda.gov,* such that the Board is able to determine that, if approved, will be developed into a viable and marketable policy consistent with Board approved procedures, these regulations, and section 508(h) of the Act.

Delivery system. The components or parties that make the policy or plan of insurance available to the public for sale.

Development. The process of composing documentation and procedures, pricing and rating methodologies, administrative and operating procedures, systems and software, supporting materials, and documentation necessary to create and implement a 508(h) submission.

Endorsement. A document that amends or revises an insurance policy reinsured under the Act in a manner that changes existing, or provides additional, coverage provided by such policy.

Expert reviewer. Independent persons contracted by the Board who meet the criteria for underwriters or actuaries that are selected by the Board to review a concept proposal, 508(h) submission, or index-based weather plan of insurance and provide advice to the Board regarding the results of their review.

FCIC. The Federal Crop Insurance Corporation, a wholly owned government corporation within USDA, whose programs are administered by RMA.

Index-based weather plan of insurance. A risk management product in which indemnities are based on a defined weather parameter exceeding or failing to meet a given threshold during a specified time period. The weather index is a proxy to measure expected loss of production when the defined weather parameter does not meet the threshold.

Limited resource producer. Has the same meaning as the term defined by USDA at: *www.lrftool.sc.egov.usda.gov/LRP_Definition.aspx* or a successor Web site.

Livestock commodity. Has the same meaning as the term in section 523(i) of the Act.

Maintenance. For the purposes of this subpart only, the process of continual support, revision or improvement, as needed, for an approved 508(h) submission, including the periodic review of premium rates and prices, updating or modifying the rating or pricing methodologies, updating or modifying policy terms and conditions, adding a new commodity under similar policy terms and conditions with similar rating and pricing methodology, or expanding a plan or policy to additional states and counties, and any other actions necessary to provide adequate, reasonable and meaningful protection for producers, ensure actuarial soundness, or to respond to statutory or regulatory changes. A concept proposal that is similar to a previously approved 508(h) submission will be considered maintenance for the similar approved 508(h) submission if submitted by the same person.

Maintenance costs. Specific expenses associated with the maintenance of an approved 508(h) submission as authorized by § 400.712.

Maintenance period. A period of time that begins on the date the Board approves the 508(h) submission and ends on the date that is not more than four reinsurance years after such approval.

Manager. The Manager of FCIC.

Marketable. A determination by the Board, based on a detailed, written marketability assessment provided in accordance with § 400.705(e), that demonstrates a sufficient number of producers will purchase the product to justify the resources and expenses required to offer the product for sale and maintain the product for subsequent years.

Multiple peril crop insurance (MPCI). Policies reinsured by FCIC that provide protection against multiple causes of loss that adversely affect production or revenue, such as to natural disasters, such as hail, drought, and floods.

National Agricultural Statistics Service (NASS). An agency within USDA, or its successor agency that collects and analyzes data collected from producers and other sources.

Non-reinsured supplemental policy (NRS). A policy, endorsement, or other risk management tool not reinsured by FCIC under the Act, that offers additional coverage, other than for loss related to hail.

Non-significant changes. Minor changes to the policy or plan of insurance, such as technical corrections, that do not affect the rating or pricing methodologies, the amount of subsidy owed, the amount or type of coverage, FCIC's reinsurance risk, or any other condition that does not affect liability or the amount of loss to be paid under the policy. Revisions to approved plans required by statutory or regulatory changes are included in this category. Changes to the policy that involve concepts that have been previously sent for expert review are also included in this category.

Plan of insurance. A class of policies, such as yield, revenue, or area based that offers a specific type of coverage to one or more agricultural commodities.

Policy. Has the same meaning as the term in section 1 of the Basic Provisions (7 CFR 457.8).

Rate of premium. The dollar amount per insured unit, or percentage rate per dollar of liability, that is needed to pay anticipated losses and provide a reasonable reserve.

Reinsurance year. The term beginning July 1 and ending on June 30 of the following year and, for reference purposes, identified by reference to the year containing June.

Related material. The actuarial documents for the insured commodity and any underwriting or loss adjustment manuals, handbooks, forms, instructions or other information needed to administer the policy.

Research. For the purposes of development, the gathering of information related to: Producer needs and interests for risk management; the marketability of the policy or plan of insurance; appropriate policy terms, premium rates, price elections, administrative and operating procedures, supporting materials, documentation, and the systems and software necessary to implement a policy or plan of insurance. The gathering of information to determine whether it is feasible to expand a policy or plan of insurance to a new area or to cover a new commodity under the same policy terms and conditions, price, and premium rates is not considered research.

Research and development costs. Specific expenses incurred and directly related to the research and development activities of a 508(h) submission as authorized in § 400.712.

Risk Management Agency (RMA). An agency within USDA that is authorized to administer the crop insurance program on behalf of FCIC.

Risk subsidy. The portion of the premium paid by FCIC on behalf of the insured.

Sales closing date. A date contained in the Special Provisions by which an application must be filed and the last date by which the insured may change the crop insurance coverage for a crop year.

Secretary. The Secretary of the United States Department of Agriculture.

Significant change. Any change to the policy or plan of insurance that may affect the rating and pricing methodologies, the amount of subsidy owed, the amount of coverage, the interests of producers, FCIC's reinsurance risk, or any condition that may affect liability or the amount of loss to be paid under the policy.

Special Provisions. Has the same meaning as the term in section 1 of the Basic Provisions (7 CFR 457.8).

Specialty crops. Fruits and vegetables, tree nuts, dried fruits, and horticulture and nursery crops (including floriculture).

Socially disadvantaged producer. Has the same meaning as section 2501(E) of the Food, Agriculture, Conservation, and Trade Act of 1990 (7 U.S.C. 2279(e)).

Standard Reinsurance Agreement (SRA). The reinsurance agreement between FCIC and the approved insurance provider, under which the approved insurance provider is authorized to sell and service eligible crop insurance contracts. For the purposes of this subpart, all references to the SRA will also include any other reinsurance agreements entered into with FCIC, including the Livestock Price Reinsurance Agreement.

Submitter. Same meaning as applicant.

Sufficient quality. A determination made by RMA and the Board that the material presented is clearly written in plain language in accordance with the Plain Writing Act of 2010 (5 U.S.C. 301), unambiguous, and is supported by detailed analysis and data so that expert reviewers, RMA and the Board can understand, comprehend and make calculations, draw substantiated conclusions or results to determine whether the 508(h) submission, concept proposal, or index-based weather plan of insurance meets the standards required for approval.

Targeted producer. Producers who are considered small, socially disadvantaged, beginning and limited resource or other specific aspects designated by FCIC for review.

USDA. The United States Department of Agriculture.

User fees. Fees, approved by the Board, that can be charged to approved insurance provider for use of a policy or plan of insurance once the period for maintenance has expired that only covers the expected maintenance costs to be incurred by the submitter.

Viable. A determination by the Board that the concept proposal, index-based weather plan of insurance, or 508(h) submission is or can be developed into a policy or plan of insurance that can be implemented by the delivery system with actuarially appropriate rates in accordance with Board procedures.

§ 400.702 Confidentiality and duration of confidentiality.

(a) Pursuant to section 508(h)(4)(A) of the Act, prior to approval by the Board, any 508(h) submission submitted to the Board under section 508(h) of the Act, concept proposal submitted under section 522 of the Act, or index-based weather plan of insurance submitted under section 523(i) of the Act, including any information generated from the 508(h) submission, concept proposal, or index-based weather plan of insurance, will be considered confidential commercial or financial information for purposes of 5 U.S.C. 552(b)(4) and will not be released by FCIC to the public, unless the applicant authorizes such release in writing.

(b) Once the Board approves a 508(h) submission or an index-based weather plan of insurance, information provided with the 508(h) submission (including information from the concept proposal) or the index-based weather plan of insurance, or generated in the approval process, may be released to the public, as applicable, including any mathematical modeling and data, unless it remains confidential business information under 5 U.S.C. 552(b)(4). While the expert reviews are releasable once the 508(h) submission or an index-based weather plan of insurance has been approved, the names of the expert reviewers may be redacted to prevent any undue pressure on the expert reviewers.

(c) Any 508(h) submission, concept proposal, or index-based weather plan of insurance disapproved by the Board will remain confidential commercial or financial information in accordance with 5 U.S.C. 552(b)(4) (no information related to such 508(h) submission, concept proposal, or index-based weather plan of insurance will be released by FCIC unless authorized in writing by the applicant).

(d) All 508(h) submissions, concept proposals, and index-based weather plans of insurance, will be kept confidential until approved by the Board and will be given an identification number for tracking purposes, unless the applicant advises otherwise.

§ 400.703 Timing and format.

(a) A 508(h) submission, concept proposal, or index-based weather plan of insurance may only be provided to FCIC during the first five business days in January, April, July, and October.

(b) A 508(h) submission, concept proposal, or index-based weather plan of insurance must be provided as an electronic file to FCIC in Microsoft Office compatible format, sent to either the address in paragraph (d)(1) or (d)(2) of this section by the due date in paragraph (a) of this section. The electronic file must contain a document with a detailed index that, in sequential order, references the location of the required information that may either be contained within the document or in a separate file. The detailed index must clearly identify each required section and include the page number if the information is contained in the document or file name if the information is contained in a separate file; and

(c) Any 508(h) submission, concept proposal, or index-based weather plan of insurance not provided within the first 5 business days of a month stated in paragraph (a) of this section will be considered to have been provided in the next month stated in paragraph (a). For example, if an applicant provides a 508(h) submission on January 10, it will be considered to have been received on April 1.

(d) Any 508(h) submission, concept proposal, or index-based weather plan of insurance must be provided to one of the following addresses, but not both:

(1) By email to the Deputy Administrator for Product Management (or successor) at *DeputyAdministrator@rma.usda.gov;* or

(2) By mail on a removable storage device such as a compact disk or

Universal Serial Bus (USB) drive, sent to the Deputy Administrator for Product Management (or any successor position), USDA/Risk Management Agency, 2312 East Bannister Road, Kansas City, MO 64131–3011.

(e) In addition to the requirements in paragraph (a) of this section, a 508(h) submission must be received not later than 240 days prior to the earliest proposed sales closing date to be considered for sale in the requested crop year.

(f) To be offered for sale in a crop year, there must be at least sixty days between the date the policy is ready to be made available for sale and the earliest sales closing date, unless this requirement is expressly waived by the Board.

(g) Notwithstanding, paragraph (f) of this section, the Board, or RMA if authorized by the Board, shall determine when sales can begin for a 508(h) submission approved by the Board after consideration of the analysis provided by the applicant AIP of the impact of the proposed implementation date on the delivery system.

§ 400.704 Covered by this subpart.

(a) An applicant may submit to the Board, in accordance with § 400.705, a 508(h) submission that is:

(1) A policy or plan of insurance not currently reinsured by FCIC;

(2) One or more proposed revisions to a policy or plan of insurance authorized under the Act; or

(3) Rates of premium for any policy or plan of insurance authorized under the Act.

(b) An applicant must submit to the Board, any significant change to a previously approved 508(h) submission, including requests for expansion, prior to making the change in accordance with § 400.705.

(c) An applicant may submit a concept proposal to the Board prior to developing a full 508(h) submission, in accordance with this subpart and the Procedures Handbook 17030—Approved Procedures for Submission of Concept Proposals Seeking Advance Payment of Research and Development Costs, which can be found on the RMA Web site at *www.rma.usda.gov.*

(d) An applicant who is an approved insurance provider may submit an index-based weather plan of insurance for consideration as a pilot program in accordance with this subpart and the Procedures Handbook 17050—Approved Procedures for Submission of Index-based Weather Plans of Insurance, which can be found on the RMA Web site at *www.rma.usda.gov.*

(e) An applicant must submit a non-reinsured supplemental policy or endorsement to RMA in accordance with § 400.713.

§ 400.705 Contents for new and changed 508(h) submissions, concept proposals, and index-based weather plans of insurance.

(a) A complete 508(h) submission must contain the following material, as applicable, submitted in accordance with § 400.703(b). A complete 508(h) submission must be a viable and marketable insurance product that protects the interests of producers, is actuarially appropriate and ensures program integrity. The material must contain adequate information as required in this section, that is presented clearly to ensure the Board and RMA can determine whether RMA and the delivery system have the resources to implement, administer, and deliver the 508(h) submission effectively and efficiently. Calculations, procedures and methodologies must be consistent throughout the submission and appropriate for the commodity and the risks covered.

(b) The first section will contain general information numbered as follows (1, 2, 3, etc.), including, as applicable:

(1) The applicant's name(s), address or primary business location, phone number, and email address;

(2) The type of 508(h) submission (see § 400.704) and a notation of whether or not the 508(h) submission was approved by the Board as a concept proposal;

(3) A statement of whether the applicant is requesting:

(i) Reinsurance;

(ii) Risk subsidy;

(iii) A&O subsidy;

(iv) Reimbursement for research and development costs, as applicable and, if the 508(h) submission was previously submitted as a concept proposal, the amount of the advance payment for expected research and development costs; or

(v) Reimbursement for expected maintenance costs, if applicable;

(4) The proposed agricultural commodities to be covered, including types, varieties, and practices covered by the 508(h) submission;

(5) The crop or insurance year and reinsurance year in which the 508(h) submission is proposed to be available for purchase by producers;

(6) The proposed sales closing date, if applicable, or the sales window or the earliest date the applicant expects to release the product to the public;

(7) The proposed states and counties where the plan of insurance is proposed to be offered;

(8) Any known or anticipated future expansion plans;

(9) Identification, including names, addresses, telephone numbers, and email addresses, of the person(s) responsible for:

(i) Addressing questions regarding the policy, underwriting rules, loss adjustment procedures, rate and price methodologies, data processing and record-keeping requirements, and any other questions that may arise in implementing or administering the program if it is approved; and

(ii) Annual reviews to ensure compliance with all requirements of the Act, this subpart, and any agreements executed between the applicant and FCIC;

(10) A statement of whether the 508(h) submission will be filed with the applicable office responsible for regulating insurance in each state proposed for insurance coverage, and if not, reasons why the 508(h) submission will not be filed for review; and

(11) A statement of whether the submitter wants the 508(h) submission to remain confidential.

(c) The second section must contain the benefits of the plan, including, as applicable, a summary that includes:

(1) How the 508(h) submission offers coverage or other benefits not currently available from existing public or private programs;

(2) How the 508(h) submission meets public policy goals and objectives consistent with the Act and other laws, as well as policy goals supported by USDA and the Federal Government; and

(3) A detailed description of the coverage provided by the 508(h) submission and its applicability to all producers, including targeted producers.

(d) Except as provided in this section, the third section must contain the policy, that is clearly written in plain language in accordance with the Plain Writing Act of 2010 (5 U.S.C. 301) such that producers will be able to understand the coverage being offered. The policy language permits actuaries to form a clear understanding of the payment contingencies for which they will set rates. The policy language does not encourage an excessive number of disputes or legal actions because of misinterpretations.

(1) If the 508(h) submission involves a new insurance policy or plan of insurance:

(i) All applicable policy provisions; and

(ii) A list of any additional coverage that may be elected by the insured in conjunction with the 508(h) submission such as applicable endorsements (include a description of the coverage and how such coverage may be obtained).

(2) If the 508(h) submission involves a change to a previously approved policy, plan of insurance, or rates of premium, the proposed revisions, rationale for each change, data and analysis supporting each change, the impact of each change, and the impact of all changes in aggregate.

(e) The fourth section must contain the following:

(1) Potential impacts the 508(h) submission may have on producers both where the new plan will and will not be available (include both positive and negative impacts) and if applicable, the reasons why the 508(h) submission is not being proposed for other areas producing the commodity;

(2) The amount of commodity (acres, head, board feet, etc.), the amount of production, and the value of each agricultural commodity proposed to be covered in each proposed county and state;

(3) A reasonable estimate of the expected number of potential buyers, liability and premium for each proposed county and state, total expected liability and premium by crop year based on the detailed assessment of producer interest, including a description of the number of producers involved in the development of the product, their level of participation, their type of participation, how many producers have provided data to assist the submitter in the development of the product, and a comparison with other similar products, including differences between the 508(h) submission and the similar products that may make participation different;

(4) If available, any insurance experience for each year and in each proposed county and state in which the policy has been previously offered for sale including an evaluation of the policy's performance and, if data are available, a comparison with other similar insurance policies reinsured under the Act;

(5) Market research studies; "market research" is the systematic gathering and interpretation of information about individuals or organizations using statistical and analytical methods and techniques of the applied social sciences to gain insight or support decision making, and that must include:

(i) Focus group results (both positive and negative reactions) where a discussion is facilitated amongst a group of stakeholders in order to gain insight into their perceptions, opinions, beliefs, and attitudes towards a product, which must include the number of focus group sessions held, where they were held, when they were held, the number of attendees at each session, the attendees affiliation (producer, agent or other), and specific feedback from the attendees regarding levels of coverage the product should include to cover anticipated risks or perils encountered, the range of costs the producer is willing to pay, what coverages the producers are specifically looking for and an assessment of whether that coverage can be provided at the price the producers are willing to pay, what shortfall or gap in risk protection the product may address, tolerance of risk, perceptions of other similar products, policy features producers may desire, and quality issues;

(ii) Other evidence the proposed 508(h) submission will be positively received by producers, agents, lending institutions, and other interested parties, including correspondence from producers, agents, grower organizations, or other stakeholders expressing the need for a certain risk management strategy, desired coverage for perils faced, and willingness to provide critical information for developing a product;

(iii) An assessment of factors that could negatively or adversely affect the market and responses from a reasonable representative cross-section of producers or significant market segment to be affected by the policy or plan of insurance; and

(iv) For 508(h) submissions proposing products for specialty crops a consultation report must be provided that includes a summary and analysis of discussions with groups representing producers of those agricultural commodities in all major producing areas for commodities to be served or potentially impacted, either directly or indirectly, and the expected impact of the proposed 508(h) submission on the general marketing and production of the crop from both a regional and national perspective including evidence that the 508(h) submission will not create adverse market distortions; and

(6) A marketability assessment from the applicant AIP who is part of the applicant and from at least one other AIP. If a marketability assessment is not provided by a separate AIP who is not part of the applicant, the applicant must provide information regarding the names of the persons and AIPs contacted and the basis for their refusal to provide the marketability assessment. The marketability assessment will include:

(i) An assessment of whether producers will buy the proposed 508(h) submission;

(ii) An assessment of whether AIPs and their agents will want to sell and service the proposed 508(h) submission;

(iii) An assessment of the risks associated with the proposed 508(h) submission and its likely effect under the SRA;

(iv) Estimated computer system impacts and costs;

(v) Estimated administrative and training requirement and costs;

(vi) An analysis of the complexity of the product; and

(vii) What, if any, efficiency will be gained or potential effects on the workload of AIPs or others participating in the program.

(f) The fifth section must contain the information related to the underwriting and loss adjustment of the 508(h) submission, prepared in accordance with the RMA–14050 Risk Management Agency External Standards Handbook located at *http://www.rma.usda.gov/handbooks/14000/index.html,* including as applicable:

(1) An underwriting guide that includes:

(i) A table of contents and introduction;

(ii) A section containing abbreviations, acronyms, and definitions;

(iii) Relevant dates, including as applicable, sales closing, cancellation, termination, earliest planting, final planting, acreage reporting, premium billing, and end of insurance;

(iv) A section containing insurance contract information (insurability requirements; producer elections, Crop Provisions not applicable to Catastrophic Risk Protection, specific unit division guidelines, etc.);

(v) Detailed rules for determining insurance eligibility, including all producer reporting requirements;

(vi) All form standards needed for inspections and producer certifications, plus detailed instructions for their use and completion;

(vii) Step-by-step examples of the data and calculations needed to establish the insurance guarantee (liability) and premium per acre or other unit of measure, including worksheets that provide the calculations in sufficient detail and in the same order as presented in the policy to allow verification that the premiums charged for the coverage are consistent with policy provisions;

(viii) A section containing any special coverage information (*i.e.,* replanting, tree replacement or rehabilitation, prevented planting, etc.), as applicable; and

(ix) A section containing all applicable reference material (*i.e.,* minimum sample requirements, row width factors, etc.).

(2) Any statements to be included in the actuarial documents including any intended Special Provisions statements that may change any underlying policy terms or conditions; and

(3) The loss adjustment standards handbook for the policy or plan of insurance that includes:

(i) A table of contents and introduction;

(ii) A section containing abbreviations, acronyms, and definitions;

(iii) A section containing insurance contract information (insurability requirements; Crop Provisions not applicable to catastrophic risk protection; specific unit division guidelines, if applicable; notice of damage or loss provisions; quality adjustment provisions; etc.);

(iv) A detailed description of the causes of loss covered by the policy or plan of insurance and any causes of loss excluded;

(v) A section that thoroughly explains appraisal methods, if applicable;

(vi) Illustrative samples of all the applicable forms needed for insuring and adjusting losses in regards to the 508(h) submission in a format compatible with the Document and Supplemental Standards Handbook (FCIC 24040) located at *http://www.rma.usda.gov/handbooks/24000/index.html,* plus detailed instructions for their use and completion;

(vii) Instructions, step-by-step examples of calculations used to determine indemnity payments for all probable situations where a partial or total loss may occur, and loss adjustment procedures that are necessary to establish the amounts of coverage and loss;

(viii) A section containing any special coverage information (*i.e.,* replanting, tree replacement or rehabilitation, prevented planting, etc.), as applicable; and

(ix) A section containing all applicable reference material (*i.e.,* minimum sample requirements, row width factors, etc.).

(g) The sixth section must contain information related to prices and rates of premium, including, as applicable:

(1) A detailed description of the premium rating methodology proposed to be used and the basis for selection of the rating methodology;

(2) A list of all assumptions made in the premium rating and commodity pricing methodologies, and the basis for these assumptions;

(3) A detailed description of the pricing and rating methodologies, including:

(i) Supporting documentation needed for the rate methodology;

(ii) All mathematical formulas and equations;

(iii) Data and data sources used in determining rates and prices and a detailed assessment of the data (including availability, access, long term reliability, and the percentage of the total commercial production that the available data represents) and how it supports the proposed rates and prices;

(iv) A detailed explanation of how the rates account for each of the risks covered by the policy; and

(v) A detailed explanation of how the prices are applicable to the policy;

(4) An example of both a rate calculation and a price calculation;

(5) A discussion of the applicant's objective evaluation of the accuracy of the data, the short and long term availability of the data, and how the data will be obtained (if the data source is confidential or proprietary explain the cost of obtaining the data); and

(6) An analysis of the results of simulations or modeling showing the performance of proposed rates and commodity prices, as applicable, based on one or more of the following (Such simulations must use all years of experience available to the applicant and must reflect both partial losses and total losses):

(i) A recalculation of total premium and losses compared to a similar or comparable insurance plan offered under the authority of the Act with modifications, as needed, to represent the components of the 508(h) submission;

(ii) A simulation that shows liability, premium, indemnity, and loss ratios for the proposed insurance product based on the probability distributions used to develop the rates and commodity prices, as applicable, including sensitivity tests that demonstrate price or yield extremes, and the impact of inappropriate assumptions; or

(iii) Any other comparable simulation that provides results indicating both aggregate and individual performance of the 508(h) submission including expected liability, premium, indemnity, and loss ratios for the proposed insurance product, under various scenarios depicting good and poor actuarial experience.

(h) The seventh section must contain the following:

(1) A statement certifying that the submitter and any approved insurance provider or its affiliates will not solicit or market the 508(h) submission until after all policy materials are released to the public by RMA, unless otherwise specified by the Board;

(2) An explanation of any provision of the policy not authorized under the Act and identification of the portion of the rate of premium due to these provisions; and

(3) Agent and loss adjuster training plans, except for 508(h) submissions proposing only changes to rates of premium to an existing policy.

(i) The eighth section must contain a statement from the submitter that, if the 508(h) submission is approved, the submitter will work with RMA and its computer programmers as needed to assure an effective and efficient implementation process. This section must also contain a description of any expected implementation or administration issues. The applicant must consult with RMA prior to providing the 508(h) submission to determine whether or not the 508(h) submission can be effectively and efficiently implemented and administered through the current information technology systems and that all reporting requirements, terminology, and dates conform to USDA standards and initiatives.

(1) If FCIC approves the 508(h) submission and determines that its information technology systems have the capacity to implement and administer the 508(h) submission, the applicant must provide a document detailing acceptable computer processing requirements consistent with those used by RMA as shown on the RMA Web site in the Appendix III/M–13 Handbook. This information details the acceptable computer processing requirements in a manner consistent with that used by RMA to facilitate the acceptance of producer applications and related data.

(2) Any computer systems, requirements, code and software must be consistent with that used by RMA and comply with the standards established in Appendix III/M–13 Handbook, or any successor document, of the SRA or other reinsurance agreement as specified by FCIC.

(3) These requirements are available from the USDA/Risk Management Agency, 2312 East Bannister Road, Kansas City, MO 64131–3011, or on RMA's Web site at *http://www.rma.usda.gov/data/m13,* or a successor Web site.

(j) The ninth section submitted on separate pages and in accordance with § 400.712 and any applicable Board procedures must specify:

(1) The following amounts, which may be limited to the amount originally

estimated in the submission, unless the applicant can justify the additional costs:

(i) For new products, the amount received for an advance payment, and a detailed estimate of the total amount of reimbursement for research and development costs; or

(ii) For products that are within the maintenance period, an estimate for maintenance costs for the year that the 508(h) submission will be effective; and

(2) A detailed estimate of maintenance costs for future years of the maintenance period and the basis that such maintenance costs will be incurred, including, but not limited to:

(i) Any anticipated expansion;

(ii) Anticipated changes or updates to policy materials;

(iii) The generation of premium rates;

(iv) The determination of prices; and

(v) Any other costs that the applicant anticipates will be requested for reimbursement of maintenance costs or expenses;

(k) The tenth section must contain executed (signed) certification statements in accordance with the following:

(1) "{Applicant's Name} hereby claim that the basis and amounts set forth in this section and § 400.712 are correct and due and owing to {Applicant's Name} by FCIC under the Federal Crop Insurance Act"; and

(2) "{Applicant Name} understands that, in addition to criminal fines and imprisonment, the 508(h) submission of false or fraudulent statements or claims may result in civil and administrative sanctions."

(l) The contents required for concept proposals are found in the Procedures Handbook 17030—Approved Procedures for Submission of Concept Proposals Seeking Advance Payment of Research and Development Costs. In addition, the proposal must provide a detailed description of why the concept provides insurance:

(1) In a significantly improved form;

(2) To a crop or region not traditionally served by the Federal crop insurance program; or

(3) In a form that addresses a recognized flaw or problem in the program;

(m) The contents required for index-based weather plans of insurance are found in the Procedures Handbook 17050—Approved Procedures for Submission of Index-based Weather Plans of Insurance. In accordance with the Board approved procedures, the approved insurance provider that submits the index-based weather plan of insurance must provide evidence they have:

(1) Adequate experience in underwriting and administering policies or plans of insurance that are comparable to the proposed policy of plan of insurance;

(2) Sufficient assets or reinsurance to satisfy the underwriting obligations of the approved insurance provider, and a sufficient insurance credit rating from an appropriate credit rating bureau; and

(3) Applicable authority and approval from each State in which the approved insurance provider intends to sell the insurance product.

§ 400.706 Review.

(a) Prior to providing a 508(h) submission, concept proposal, or index-based weather plan of insurance to the Board, RMA will:

(1) Review the 508(h) submission, concept proposal, or index-based weather plan of insurance to determine if all required documentation is included in accordance with § 400.705;

(2) Review the 508(h) submission, concept proposal, or index-based weather plan of insurance to determine whether it is of sufficient quality to conduct a meaningful review such that the Board will be able to make an informed decision regarding approval or disapproval;

(3) In accordance with section 508(h)(1)(B) of the Act, at its sole discretion, determine if the policy or plan of insurance:

(i) Will likely result in a viable and marketable policy;

(ii) Will provide crop insurance coverage in a significantly improved form; and

(iii) Adequately protect the interests of producers.

(4) RMA may reject and return any 508(h) submission, concept proposal, or index based weather plan of insurance that:

(i) Is not complete;

(ii) Is unlikely to result in a viable and marketable policy;

(iii) Will not provide crop insurance coverage in a significantly improved form; and

(iv) Will not adequately protect the interests of producers.

(5) Except as provided in paragraph (a)(4) of this section, forward the 508(h) submission, concept proposal, or index-based weather plan of insurance, and the results of RMA's initial review, to the Board for its determination of completeness and quality.

(b) Upon the Board's receipt of a 508(h) submission, the Board will:

(1) Determine if the 508(h) submission is complete (the date the Board votes to contract with expert reviewers is the date the 508(h) submission is deemed to be complete for the start of the 120 day time-period for approval);

(2) Unless the 508(h) submission makes non-significant changes to a policy or plan of insurance, or involves policy provisions that have already undergone expert review, forward the complete 508(h) submission to at least five expert reviewers to review the 508(h) submission:

(i) Of the five expert reviewers, no more than one will be employed by the Federal Government, and none may be employed by any approved insurance provider or their representative; and

(ii) The expert reviewers will each provide their individual assessment of whether the 508(h) submission:

(A) Protects the interests of agricultural producers and taxpayers;

(B) Is actuarially appropriate;

(C) Follows recognized insurance principles;

(D) Meets the requirements of the Act;

(E) Does not contain excessive risks (risks may be considered excessive if they encourage adverse selection, moral hazard, or if premium rates cannot be adequately or appropriately determined);

(F) Follows sound, reasonable, and appropriate underwriting principles;

(G) Will provide a new kind of coverage that is likely to be viable and marketable;

(H) Will provide crop insurance coverage in a manner that addresses a clear and identifiable flaw or problem in an existing policy;

(I) Will provide a new or improved coverage for a commodity that previously had no available crop insurance, or has demonstrated a low level of participation or coverage level under existing coverage;

(J) May have a significant adverse impact on the crop insurance delivery system;

(K) The marketability assessment reasonably demonstrates the product would be viable and marketable (if the applicant cannot obtain a marketability assessment by another AIP, the Board shall presume that the submission is unmarketable);

(L) If applicable, contains a consultation report that provides evidence the 508(h) submission will not create adverse market distortions; and

(M) Meets any other criteria the Board may deem necessary;

(3) Return to the applicant any 508(h) submission the Board determines is not complete, along with an explanation of the reason for the determination and:

(i) With respect to 508(h) submissions developed from approved concept proposals, the provisions in § 400.712(c)(1) shall apply; and

(ii) Except for 508(h) submissions developed from concept proposals, if the 508(h) submission is resubmitted at a later date, it will be considered a new 508(h) submission solely for the purpose of determining the amount of time that the Board must take action; and

(4) For complete 508(h) submissions:

(i) Request review by RMA to provide its assessment of whether the 508(h) submission:

(A) Meets the criteria listed in subsections (b)(2)(ii)(A) through (M);

(B) Is consistent with USDA's public policy goals;

(C) Does not increase or shift risk to any other FCIC reinsured policy;

(D) Can be implemented, administered, and delivered effectively and efficiently using RMA's information technology and delivery systems; and

(E) Contains requested amounts of government reinsurance, risk subsidy, and administrative and operating subsidies that are reasonable and appropriate for the type of coverage provided by the policy; and

(ii) Seek review from the Office of the General Counsel (OGC) to determine if the 508(h) submission conforms to the requirements of the Act and all applicable Federal statutes and regulations.

(c) Upon the Board's receipt of a concept proposal, the Board will:

(1) Determine whether the concept proposal is complete (the date the Board votes to contract with expert reviewers is the date the concept proposal is deemed to be a complete concept proposal for the start of the 120 day time-period for approval);

(2) If complete, forward the concept proposal to at least two expert reviewers with underwriting or actuarial experience to review the concept in accordance with section 522(b)(2) of the Act, this subpart, and Procedures Handbook 17030—Approved Procedures for Submission of Concept Proposals Seeking Advance Payment of Research and Development Costs;

(3) Return to the applicant any concept proposal the Board determines is not complete, along with an explanation of the reason for the determination (If the concept proposal is resubmitted at a later date, it will be considered a new concept proposal solely for the purposes of determining the amount of time that the Board must take action);

(4) Determine whether the concept proposal, if developed into a policy or plan of insurance would, in good faith, would meet the requirement of being likely to result in a viable and marketable policy consistent with section 508(h) (if the applicant cannot obtain a marketability assessment by another AIP, the Board shall presume that the submission is unmarketable);

(5) At its sole discretion, determine whether the concept proposal, if developed into a policy or plan of insurance would meet the requirement of providing coverage:

(i) In a significantly improved form;

(ii) To a crop or region not traditionally served by the Federal crop insurance program; or

(iii) In a form that addresses a recognized flaw or problem in the program;

(6) Determine whether the proposed budget and timetable are reasonable;

(7) Determine whether the concept proposal meets all other requirements imposed by the Board or as otherwise specified in Procedures Handbook 17030—Approved Procedures for Submission of Concept Proposals Seeking Advance Payment of Research and Development Costs; and

(8) Provide a date by which the 508(h) submission must be provided in consultation with the applicant.

(d) Upon the Board's receipt of an index-based weather plan of insurance, the Board will:

(1) Determine whether the index-based weather plan of insurance is complete (the date the Board votes to contract with expert reviewers is the date the index-based weather plan of insurance is deemed to be complete for the start of the 120-day time-period for approval);

(2) If determined to be complete, contract with five expert reviewers and review the index-based weather plan of insurance in accordance with section 523(i) of the Act, this subpart, and Procedures Handbook 17050—Approved Procedures for Submission of Index-based Weather Plans of Insurance;

(3) Return to the applicant any index-based weather plan of insurance the Board determines is not complete, along with an explanation of the reason for the determination (if the index-based weather plan of insurance is resubmitted at a later date, it will be considered a new index-based weather plan of insurance solely for the purposes of determining the amount of time that the Board must take action); and

(4) Give the highest priority for approval of index-based weather plans of insurance that provide a new kind of coverage for specialty crops and livestock commodities that previously had no available crop insurance, or have demonstrated a low level of participation under existing coverage.

(e) All comments and evaluations will be provided to the Board by a date determined by the Board to allow the Board adequate time for review.

(f) The Board will consider all comments, evaluations, and recommendations in its review process. Prior to making a decision, the Board may request additional information from RMA, OGC, the expert reviewers, or the applicant.

(g) In considering whether to approve policies or plans of insurance and when such policies or plans of insurance will be offered for sale, the Board will:

(1) First, consider policies or plans of insurance that address underserved commodities, including commodities for which there is no insurance;

(2) Second, consider existing policies or plans of insurance for which there is inadequate coverage or there exists low levels of participation; and

(3) Last, consider all policies or plans of insurance submitted to the Board that do not meet the criteria described in paragraph (g)(1) or (2) of this section.

(h) At any time an applicant may request a time delay after the 508(h) submission, concept proposal, or index-based weather plan of insurance has been placed on the Board meeting agenda. The Board is not required to agree to such an extension.

(1) With respect to 508(h) submissions from concept proposals approved by the Board for advanced payment, the applicant must provide good cause why consideration should be delayed.

(2) Any requested time delay is not limited in the length of time unless a date is set by the Board by which all revisions to the 508(h) submission, concept proposal or index-based weather plan of insurance must be made. However, delays may make implementation of the 508(h) submission for the targeted crop year impractical or impossible as determined by the Board.

(3) The time period during which the Board will make a decision to approve or disapprove the 508(h) submission, concept proposal or index-based weather plan of insurance shall be extended commensurately with any time delay requested by the applicant.

(i) The applicant may withdraw a 508(h) submission, concept proposal, index-based weather plan of insurance, or a portion of a 508(h) submission or concept proposal, at any time by presenting a request to the Board. A withdrawn 508(h) submission, concept proposal or index-based weather plan of insurance that is resubmitted will be deemed a new 508(h) submission, concept proposal, or index-based weather plan of insurance solely for the purposes of determining the amount of time that the Board must take action.

(j) The Board will render a decision on a 508(h) submission or index-based weather plan of insurance, with or without revision or give notice of intent to disapprove within 90 days after the date the 508(h) submission or index-based weather plan of insurance is considered complete by the Board, unless the Board agrees to a time delay in accordance with paragraph (h) of this section.

(k) The Board may provide a notice of intent to disapprove a 508(h) submission if it determines:

(1) The interests of producers and taxpayers are not protected, including but not limited to:

(i) The 508(h) submission does not provide adequate coverage or treats producers disparately;

(ii) The applicant has not presented sufficient documentation that the 508(h) submission will provide a new kind of coverage that is likely to be viable and marketable (if the applicant cannot obtain a marketability assessment by another AIP, the Board shall presume that the submission is unmarketable);

(iii) Coverage would be similar to another policy or plan of insurance that has not demonstrated a low level of participation or does not contain a clear and identifiable flaw, and the producer would not significantly benefit from the 508(h) submission;

(iv) The 508(h) submission may create adverse market distortions or adversely impact other crops or agricultural commodities if marketed;

(v) The 508(h) submission will have a significant adverse impact on the private delivery system;

(vi) The 508(h) submission cannot be implemented, administered, and delivered effectively and efficiently using RMA's information technology and delivery systems;

(vii) The 508(h) submission contains flaws that may encourage adverse selection or moral hazard; or

(viii) The 508(h) submission contains vulnerabilities that allow indemnities to exceed the value of the crop;

(2) The premium rates are not actuarially appropriate;

(3) The 508(h) submission does not conform to sound insurance and underwriting principles;

(4) The risks associated with the 508(h) submission are excessive or it increases or shifts risk to another reinsured policy;

(5) The 508(h) submission does not meet the requirements of the Act; or

(6) The 90-day deadline under subsection (j) will expire before the Board has time to make an informed decision to approve or disapprove the 508(h) submission.

(l) The Board may disapprove a concept proposal if it determines:

(1) The concept, in good faith, will not likely result in a viable and marketable policy consistent with section 508(h);

(2) At the sole discretion of the Board, the concept, if developed into a policy and approved by the Board, would not provide crop insurance coverage:

(i) In a significantly improved form;

(ii) To a crop or region not traditionally served by the Federal crop insurance program; or

(iii) In a form that addresses a recognized flaw or problem in the program;

(3) The proposed budget and timetable are not reasonable, as determined by the Board; or

(4) The concept proposal fails to meet one or more requirements established by the Board.

(m) The Board shall provide a notice of intent to disapprove an index-based weather plan of insurance if it determines there is not:

(1) Adequate experience in underwriting and administering policies or plans of insurance that are comparable to the proposed policy or plan of insurance;

(2) Sufficient assets or reinsurance to satisfy the underwriting obligations of the approved insurance provider, and possess a sufficient insurance credit rating from an appropriate credit rating bureau, in accordance with Board procedures; and

(3) Applicable authority and approval from each State in which the approved insurance provider intends to sell the insurance product.

(n) Unless otherwise provided for in this section:

(1) If the Board intends to disapprove a 508(h) submission or index-based weather plan of insurance, the Board will provide the applicant with a written explanation outlining the basis for the intent to disapprove; and

(2) Any approval or disapproval of a 508(h) submission, concept proposal, or index-based weather plan of insurance must be made by the Board in writing not later than 120 days after the Board has determined it to be complete.

(o) If a notice of intent to disapprove all or part of a 508(h) submission or index-based weather plan of insurance has been provided by the Board, the applicant must provide written notice to the Board not later than 30 days after the Board provides such notice if the 508(h) submission or index-based weather plan of insurance will be modified. If the applicant does not respond within the 30-day period, the Board will send the applicant a letter stating the 508(h) submission or index-based weather plan of insurance is disapproved.

(p) If the applicant elects to modify the 508(h) submission or index-based weather plan of insurance:

(1) The applicant must advise the Board of a date by which the modified 508(h) submission or index-based weather plan of insurance will be presented to the Board; and

(2) The remainder of the time left between the Board's notice of intent to disapprove and the expiration of the 120-day deadline is paused until the modified 508(h) submission or index-based weather plan of insurance is received by the Board.

(3) The Board will disapprove a modified 508(h) submission or index-based weather plan of insurance if the:

(i) Causes for disapproval stated by the Board in its notification of intent to disapprove the 508(h) submission or index-based weather plan of insurance are not satisfactorily addressed;

(ii) Board determines there is insufficient time for the Board to finish its review before the expiration of the 120-day deadline for disapproval of a 508(h) submission or index-based weather plan of insurance, unless the applicant grants the Board an extension of time to adequately consider the modified 508(h) submission or index-based weather plan of insurance (If an extension of time is agreed upon, the time period during which the Board must act on the modified 508(h) submission or index-based weather plan of insurance will paused during the extension); or

(iii) Applicant does not present a modification of the 508(h) submission or index-based weather plan of insurance to the Board on the date the applicant specified and the applicant does not request an additional time delay.

(q) If the Board fails to render a decision on a new 508(h) submission or index-based weather plan of insurance within the time periods specified in paragraph (j) or (n) of this section, such 508(h) submission or index-based weather plan of insurance will be deemed approved by the Board for the initial reinsurance year designated for the 508(h) submission or index-based weather plan of insurance. The Board must approve the 508(h) submission or index-based weather plan of insurance for it to be available for any subsequent reinsurance year.

§ 400.707 Presentation to the Board for approval or disapproval.

(a) The Board will inform the applicant of the date, time, and place of the Board meeting.

(b) The applicant will be given the opportunity and is encouraged to present the 508(h) submission, concept proposal, or index-based weather plan of insurance to the Board in person. The applicant must confirm in writing, email or fax whether the applicant will present in person to the Board.

(c) If the applicant elects not to present the 508(h) submission, concept proposal, or index-based weather plan of insurance to the Board, the Board will make its decision based on the information provided in accordance with § 400.705 and § 400.706.

§ 400.708 Post approval.

(a) After a 508(h) submission is approved by the Board, and prior to it being made available for sale to producers:

(1) The following must be executed, as applicable:

(i) If required by FCIC, an agreement between the applicant and FCIC that specifies:

(A) In addition to the requirements in § 400.709, responsibilities of each with respect to the implementation, delivery and maintenance of the 508(h) submission; and

(B) The required timeframes for submitting any information and documentation needed to administer the approved 508(h) submission;

(ii) A reinsurance agreement if the approved submission does not meet, or is not expected to perform in a financial manner consistent with the terms and conditions of the Standard Reinsurance Agreement or any other existing reinsurance agreement offered by FCIC in effect for the crop year, and that considers the interests of all participating AIPs; and

(iii) A training package to facilitate implementation of the approved 508(h) submission;

(2) The Board may limit the availability of coverage, for any policy or plan of insurance developed under the authority of the Act and this regulation, on any farm or in any county or area;

(3) A 508(h) submission approved by the Board under this subpart will be made available to all approved insurance providers under the same reinsurance, subsidy, and terms and conditions as received by the applicant;

(4) Any solicitation, sales, marketing, or advertising of the approved 508(h) submission by the applicant before FCIC has made the policy materials available to all interested parties through its official issuance system will result in the denial of reinsurance, risk subsidy, and A&O subsidy for those policies affected; and

(5) The property rights to the 508(h) submission will automatically transfer to FCIC if the applicant elects not to maintain the 508(h) submission under § 400.712(a)(3) or fails to notify FCIC of its decision to elect or not elect maintenance of the program under § 400.712(l).

(b) Requirements and procedures for approved index-based weather plans of insurance are contained in Procedures Handbook 17050—Approved Procedures for Submission of Index-based Weather Plans of Insurance. In accordance with the Board approved procedures, index-based weather plans of insurance are not eligible for federal reinsurance, but may be approved for risk subsidy and A&O subsidy.

§ 400.709 Roles and responsibilities.

(a) With respect to the applicant:

(1) The applicant is responsible for:

(i) Preparing and ensuring that all policy documents, rates of premium, prices, and supporting materials, including actuarial documents, are submitted by the deadline specified by FCIC, in the form approved by the Board, and are in compliance with section 508 of the Rehabilitation Act;

(ii) Annually updating and providing maintenance changes no later than 180 days prior to the earliest contract change date for the commodity in all counties or states in which the policy or plan of insurance is sold;

(iii) Timely addressing questions, problems or clarifications in regard to a policy or plan of insurance (all such resolutions for approved 508(h) submissions will be communicated to all approved insurance providers through FCIC's official issuance system); and

(iv) If requested by the Board, providing an annual review of the policy's performance, in writing to the Board, 180 days prior to the contract change date for the plan of insurance (The first annual report will be submitted one full year after implementation of an approved policy or plan of insurance, as agreed to by the submitter and RMA);

(2) Only the applicant may make changes to the policy, plan of insurance, or rates of premium approved by the Board:

(i) Any changes to approved 508(h) submissions, both non-significant and significant, must be submitted to FCIC in the form of a 508(h) submission for review in accordance with this subpart no later than 180 days prior to the earliest contract change date for the commodity in all counties or states in which the policy or plan of insurance is sold; and

(ii) Significant changes will be considered a new 508(h) submission;

(3) Except as provided in paragraph (a)(4) of this section, the applicant is solely liable for any mistakes, errors, or flaws in the submitted policy, plan of insurance, their related materials, or the rates of premium that have been approved by the Board unless, or until, the policy or plan of insurance is transferred to FCIC in accordance with § 400.712(l) (the applicant remains liable for any mistakes, errors, or flaws that occurred prior to transfer of the policy or plan of insurance to FCIC);

(4) If the mistake, error, or flaw in the policy, plan of insurance, their related materials, or the rates of premium is discovered more than 45 days prior to the cancellation or termination date for the policy or plan of insurance, the applicant may request in writing that FCIC withdraw the approved policy, plan of insurance, or rates of premium:

(i) Such request must state the discovered mistake, error, or flaw in the policy, plan of insurance, or rates of premium, and the expected impact on the program; and

(ii) For all timely received requests for withdrawal, no liability will attach to such policies, plans of insurance, or rates of premium that have been withdrawn and no producer, approved insurance provider, or any other person will have a right of action against the applicant;

(5) Notwithstanding the policy provisions regarding cancellation, any policy, plan of insurance, or rates of premium that have been withdrawn by the applicant, in accordance with paragraph (a)(4) of this section is deemed canceled and applications are deemed not accepted as of the date that FCIC publishes the notice of withdrawal on its Web site at *www.rma.usda.gov.*

(i) Approved insurance providers will be notified in writing by FCIC that the policy, plan of insurance, or premium rates have been withdrawn; and

(ii) Producers will have the option of selecting any other policy or plan of insurance authorized under the Act that is available in the area by the sales closing date for such policy or plan of insurance; and

(6) Failure of the applicant to perform all of the applicant's responsibilities may result in the withdrawal of approval for the policy or plan of insurance.

(b) With respect to FCIC:

(1) FCIC is responsible for:

(i) Conducting a review in accordance with § 400.706 and providing its recommendations to the Board;

(ii) With respect to 508(h) submissions:

(A) Ensuring that all approved insurance providers receive the approved policy or plan of insurance, and related material, for sale to producers in a timely manner (All such information shall be communicated to all approved insurance providers through FCIC's official issuance system);

(B) As applicable, ensuring that approved insurance providers receive reinsurance under the same terms and conditions as the applicant (Approved insurance providers should contact FCIC to obtain and execute a copy of the reinsurance agreement) if required; and

(C) Reviewing the activities of approved insurance providers, agents, loss adjusters, and producers to ensure that they are in accordance with the terms of the policy or plan of insurance, the reinsurance agreement, and all applicable procedures;

(2) FCIC will not be liable for any mistakes, errors, or flaws in the policy, plan of insurance, their related materials, or the rates of premium and no cause of action may be taken against FCIC as a result of such mistake, error, or flaw in a 508(h) submission or index-based weather plan of insurance submitted under this subpart;

(3) If at any time prior to the cancellation date, FCIC discovers there is a mistake, error, or flaw in the policy, plan of insurance, their related materials, or the rates of premium, or any other reason for withdrawal of approval contained in § 400.706(k) exists, FCIC will withdraw reinsurance for such policy or plan of insurance to all AIPs for the subsequent crop year (If reinsurance is denied, a written notice will be provided on RMA's Web site at *www.rma.usda.gov*);

(4) If maintenance of the policy or plan of insurance is transferred to FCIC in accordance with § 400.712(l), FCIC will assume liability for the policy or plan of insurance for any mistake, error, or flaw that occur after the date the policy is transferred.

(c) If approval by the Board is withdrawn or reinsurance is denied for any 508(h) submission, RMA will provide such notice on its Web site and the approved insurance provider must cancel the policy or plan of insurance in accordance with its terms.

§ 400.710 Preemption and premium taxation.

A policy or plan of insurance that is approved by the Board for FCIC reinsurance is preempted from state and local taxation. This preemption does not apply to index-based weather plans of insurance approved for premium subsidy or A&O subsidy under this part.

§ 400.711 Right of review, modification, and the withdrawal of approval.

(a) At any time after approval, the Board may review any policy, plan of insurance, related material, or rates of premium approved under this subpart, including index-based weather plans of insurance and request additional information to determine whether the policy, plan of insurance, related material, or rates of premium comply with the requirements of this subpart.

(b) The Board will notify the applicant of any problem or issue that may arise and allow the applicant an opportunity to make any needed change. If the contract change date has passed, the applicant will be liable for such problems or issues for the crop year in accordance with § 400.709 until the policy may be changed.

(c) The Board may withdraw approval for the applicable policy, plan of insurance or rate of premium, including index-based weather plans of insurance, as applicable, if:

(1) The applicant fails to perform the responsibilities stated under § 400.709(a);

(2) The applicant does not timely and satisfactorily provide materials or resolve any issue to the Board's satisfaction so that necessary changes can be made prior to the earliest contract change date;

(3) The Board determines the applicable policy, plan of insurance or rate of premium, including index-based weather plans of insurance is not in conformance with the Act, these regulations or the applicable procedures;

(4) The policy, plan of insurance, or rates of premium are not sufficiently marketable according to the applicant's estimate or fails to perform sufficiently as determined by the Board; or

(5) The interest of producers or tax payers is not protected or the continuation of the program raises questions or issues of program integrity.

§ 400.712 Research and development reimbursement, maintenance reimbursement, advance payments for concept proposals, and user fees.

(a) For 508(h) submissions approved by the Board for reinsurance under section 508(h) of the Act:

(1) The 508(h) submission may be eligible for a one-time payment of research and development costs and reimbursement of maintenance costs for up to four reinsurance years, as determined by the Board;

(2) Reimbursement of research and development costs or maintenance costs will be considered as payment in full by FCIC for the 508(h) submission, and no additional amounts will be owed to the applicant if the 508(h) submission is transferred to FCIC in accordance with paragraph (l) of this section; and

(3) If the applicant elects at any time not to continue to maintain the 508(h) submission, it will automatically become the property of FCIC and the applicant will no longer have any property rights to the 508(h) submission and will not receive any user fees for the plan of insurance;

(b) The Board approved procedures and time-frames must be followed, or research and development costs and maintenance costs may not be reimbursed.

(1) After a 508(h) submission has been approved by the Board for reinsurance, to be considered for reimbursement of:

(i) Research and development costs, the applicant must submit the total amount requested and all supporting documentation to FCIC by electronic method or by hard copy and such information must be received by FCIC on or before August 1 immediately following the date the 508(h) submission was released to approved insurance providers through FCIC's issuance system; or

(ii) Maintenance costs, the applicant must submit the total amount requested and all supporting documentation to FCIC by electronic method or by hard copy and such information must be received by FCIC on or before August 1 of each year of the maintenance period.

(2) Given the limitation on funds, regardless of when the request is received, no payment will be made prior to September 15 of the applicable fiscal year.

(c) Applicants submitting a concept proposal may request an advance payment of up to 50 percent of the projected total research and development costs, and after the applicant has begun research and development activities, the Board may, at its sole discretion, provide up to an additional 25 percent advance payment of the estimated research and development costs, if the requirements in the definition of advance payment are met and the additional advance payment is requested in accordance with Procedures Handbook 17030—Approved Procedures for Submission of Concept Proposals Seeking Advance Payment of Research and Development Costs.

(1) If a concept proposal is approved by the Board for advance payment, the applicant is responsible for

independently developing a 508(h) submission that is complete as specified in this subpart by the deadline set by the Board.

(i) If an applicant fails to fulfill the obligation to provide a 508(h) submission that is complete by the deadline set by the Board, the Board shall provide a notice of non-compliance to the applicant and allow not less than 30 days for the applicant to respond;

(ii) If the applicant fails to respond, to the satisfaction of the Board, with just cause as to why a 508(h) submission that is complete was not provided by the deadline set by the Board, the applicant shall return the amount of the advance payment plus interest at the rate of 1.25 percent simple interest per calendar month;

(iii) If the applicant responds, to the satisfaction of the Board, with just cause as to why a 508(h) submission that is complete was not provided by the deadline set by the Board, the applicant will be given a new deadline by which to provide a 508(h) submission that is complete; and

(iv) If the applicant fails to provide a 508(h) submission that is complete by the deadline, no additional extensions will be approved by the Board and the applicant shall return the amount of the advance payment plus interest at the rate of 1.25 percent simple interest per calendar month.

(2) If an applicant receives an advance payment for a portion of the expected research and development costs for a concept proposal that is developed into a 508(h) submission and determined by the Board to be complete, but the 508(h) submission is not approved by the Board following expert review, the Board will not:

(i) Seek a refund of any advance payments for research and development costs; and

(ii) Make any further research and development cost reimbursements associated with the 508(h) submission.

(d) Under section 522 of the Act, there are limited funds available on an annual fiscal year basis to pay for reimbursements of research and development costs (including advance payments for concept proposals) and maintenance costs. Consistent with paragraphs (e) through (j) of this section if all applicants' requests for reimbursement of research and development costs (including advance payments for concept proposals) and maintenance costs in any fiscal year:

(1) Do not exceed the maximum amount authorized by law, the applicants may receive the full amount of reimbursement determined reasonable by the Board; or

(2) Exceed the amount authorized by law, each applicant's reimbursement determined reasonable by the Board will be determined by dividing the total amount of each individual applicant's reimbursable costs authorized in paragraphs (e) through (j) of this section by the total amount of the aggregate of all applicants' reimbursable costs authorized in paragraphs (e) through (j) for the year and multiplying the result by the amount of reimbursement authorized under the Act.

(e) The amount of reimbursement for research and development costs and maintenance costs requested by the applicant may be reduced as necessary when the requested amount is not commensurate with the complexity or the size of the area proposed to be covered.

(f) Research and development costs and maintenance costs must be supported by itemized statements and supporting documentation (copies of contracts, billing statements, time sheets, travel vouchers, accounting ledgers, etc.).

(1) Actual costs submitted will be examined for reasonableness and may be adjusted at the sole discretion of the Board.

(2) Allowable research and development costs and maintenance costs (directly related to research and development or maintenance of the 508(h) submission only) may include the following:

(i) Wages and benefits, exclusive of bonuses, overtime pay, or shift differentials;

(A) One line per employee or contractor, include job title, total hours, and total dollars;

(B) The rates charged must be commensurate with the tasks performed (For example, a person performing the task of data entry should not be paid at the rate for performing data analysis);

(C) The wage rate and benefits shall not exceed two times the hourly wage rate plus benefits provided by the Bureau of Labor Statistics; and

(D) The applicant must report any familial or business relationship that exists between the applicant and the contractor or employee (Reimbursement may be limited or denied if the contractor or employee is associated to the applicant and they may be considered as one and the same. This includes a separate entity being created by the applicant to conduct research and development. Reimbursement may be limited or denied if the contractor is paid a salary or other compensation);

(ii) Travel and transportation (One line per event, include the job title, destination, purpose of travel, lodging cost, mileage, air or other identified transportation costs, food and miscellaneous expenses, other costs, and the total cost);

(iii) Software and computer programming developed specifically to determine appropriate rates, prices, or coverage amounts (Identify the item, include the purpose, and provide receipts or contract or straight-time hourly wage, hours, and total cost. Software developed to send or receive data between the producer, agent, approved insurance provider or RMA or such other similar software may not be included as an allowable cost);

(iv) Miscellaneous expenses such as postage, telephone, express mail, and printing (Identify the item, cost per unit, number of items, and total dollars); and

(v) Training costs expended to facilitate implementation of a new approved 508(h) submission (Include instructor(s) hourly rate, hours, and cost of materials and travel) conducted at a national level, directed to all approved insurance providers interested in selling the 508(h) submission, and approved prior to the training by RMA).

(3) The following expenses are specifically not eligible for research and development and maintenance cost reimbursement:

(i) Copyright fees, patent fees, or any other charges, costs or expenses related to the use of intellectual property;

(ii) Training costs, excluding training costs to facilitate implementation of the approved 508(h) submission in accordance with subsection (f)(2)(v);

(iii) State filing fees and expenses;

(iv) Normal ongoing administrative expenses or indirect overhead costs (for example, costs associated with the management or general functions of an organization, such as costs for internet service, telephone, utilities, and office supplies);

(v) Paid or incurred losses;

(vi) Loss adjustment expenses;

(vii) Sales commission;

(viii) Marketing costs;

(ix) Lobbying costs;

(x) Product or applicant liability resulting from the research, development, preparation or marketing of the policy;

(xi) Copyright infringement claims resulting from the research, development, preparation or marketing of the policy;

(xii) Costs of making program changes as a result of any mistakes, errors or flaws in the policy or plan of insurance;

(xiii) Costs associated with building rents or space allocation;

(xiv) Costs in paragraphs (i) and (j) of this section determined by the Board to be ineligible for reimbursement; and

(xv) Local, State, or Federal taxes.

(g) Requests for reimbursement of maintenance costs must be supported by itemized statements and supporting documentary evidence for each reinsurance year in the maintenance period.

(1) Actual costs submitted will be examined for reasonableness and may be adjusted at the sole discretion of the Board.

(2) Maintenance costs for the following activities may be reimbursed:

(i) Expansion of the original 508(h) submission into additional crops, counties or states;

(ii) Non-significant changes to the policy and any related material;

(iii) Non-significant or significant changes to the policy as necessary to protect program integrity or as required by Congress; and

(iv) Any other activity that qualifies as maintenance.

(h) Projected costs for research and development for concept proposals shall be based on a detailed estimate of the costs allowed in paragraph (f) of this section. Since costs are one measurement of the viability to develop an efficient policy, the Board may limit reimbursements for research and development to the estimated costs contained in the concept proposal, unless the submitter can justify a higher reimbursement in accordance with Board procedures.

(i) If a 508(h) submission is determined to be incomplete and is subsequently resubmitted and approved, the costs to perfect the 508(h) submission may not be considered reimbursable costs depending on the level of insufficiency or incompleteness of the 508(h) submission, as determined at the sole discretion of the Board.

(j) Reimbursement of costs associated with addressing issues raised by the Board, expert reviewers and RMA will be evaluated based on the substance of the issue and the amount of time reasonably necessary to address the specific issue. Delays and additional costs caused by the inability or refusal to adequately address issues may not be considered reimbursable, as determined at the sole discretion of the Board.

(k) If the Board withdraws its approval for reinsurance at any time during the period that reimbursement for maintenance is being made or user fees are being collected, no maintenance reimbursement shall be made nor any user fee be owed after the date of such withdrawal.

(l) Not later than 180 days prior to the end of the last reinsurance year in which a maintenance reimbursement will be paid for the approved 508(h) submission, the applicant must notify FCIC in writing regarding its decision on future ownership and maintenance of the policy or plan of insurance.

(1) The applicant must notify FCIC in writing whether it intends to:

(i) Continue to maintain the policy or plan of insurance and charge approved insurance providers a user fee to cover maintenance expenses for all policies earning premium; or

(ii) Transfer responsibility for maintenance to FCIC.

(2) If the applicant fails to notify FCIC in writing by the deadline, the policy or plan of insurance will automatically transfer to FCIC beginning with the next reinsurance year.

(3) If the applicant elects to:

(i) Continue to maintain the policy or plan of insurance, the applicant must submit a request for approval of the user fee by the Board at the time of the election; or

(ii) Transfer the policy or plan of insurance to FCIC, FCIC may at its sole discretion, continue to maintain the policy or plan of insurance or elect to withdraw the availability of the policy or plan of insurance.

(4) Requests for approval of the user fee must be accompanied by written documentation to support the amount requested will only cover direct costs to maintain the plan of insurance. Costs that are not eligible for research and development and maintenance reimbursements under this section are not eligible to be considered for determining the user fee.

(5) The Board will approve the amount of user fee, including the maximum amount of total maintenance that may be collected per year, that is payable to the applicant by approved insurance providers unless the Board determines that the user fee charged:

(i) Is unreasonable in relation to the maintenance costs associated with the policy or plan of insurance; or

(ii) Unnecessarily inhibits the use of the policy or plan of insurance by approved insurance providers.

(6) If the total user fee exceeds the maximum amount determined by the Board, the maximum amount determined by the Board will be divided by the number of policies earning premium to determine the amount to be paid by each approved insurance provider.

(7) Reasonableness of the initial request to charge a user fee will be determined by the Board based on a comparison of the amount of reimbursement for maintenance previously received, the number of policies, the number of approved insurance providers, and the expected total amount of user fees to be received in any reinsurance year.

(8) A user fee unnecessarily inhibits the use of a policy or plan of insurance if it is so high that approved insurance providers will not sell the policy, or the user fee represents an unreasonable portion of the A&O subsidy paid to the AIP such that it prevents the AIP from meeting its other obligations under the SRA.

(9) The user fee charged to each approved insurance provider will be considered payment in full for the use of such policy, plan of insurance or rate of premium for the reinsurance year in which payment is made.

(10) It is the sole responsibility of the applicant to collect such fees from an approved insurance provider and any indebtedness for such fees must be resolved by the applicant and approved insurance provider.

(i) Applicants may request that FCIC provide the number of policies sold by each approved insurance provider.

(ii) Such information will be provided not later than 90 days after such request is made or not later than 90 days after the requisite information has been provided to FCIC by the approved insurance provider, whichever is later.

(11) Every two years after approval of a user fee, or if the applicant has made a significant change to the approved 508(h) submission, applicants must submit documentation to the Board for review in determining if the user fee should be revised.

(12) The Board may review the amount of the user fee at any time at its sole discretion.

(m) The Board may consider information from the Equal Access to Justice Act, 5 U.S.C. 504, the Bureau of Labor Statistic's Occupational Employment Statistics Survey, the Bureau of Labor Statistic's Employment Cost Index, and any other information determined applicable by the Board, in making a determination whether to approve a 508(h) submission for reimbursement of research and development costs, maintenance costs, or user fees.

(n) For purposes of this section, rights to, or obligations of, research and development cost reimbursement, maintenance cost reimbursement, or user fees cannot be transferred from any individual or entity unless specifically approved in writing by the Board.

(o) Applicants requesting reimbursement for research and development costs, maintenance costs, or user fees, may present their request in person to the Board prior to consideration for approval.

(p) Index-based weather plans of insurance are not eligible for reimbursement from FCIC for maintenance costs or research and development costs. Submitters of approved index-based weather plans of insurance may collect user fees from other approved insurance providers in accordance with Procedures Handbook 17050—Approved Procedures for Submission of Index-based Weather Plans of Insurance.

§ 400.713 Non-reinsured supplemental (NRS) policy.

(a) Unless otherwise specified by FCIC, any NRS policy that covers the same agricultural commodity as any policy reinsured by FCIC under the Act must be provided to RMA to ensure it does not shift any loss or risk that does not exist under the FCIC reinsured policy. Failure to provide such NRS policy or endorsement to RMA prior to its issuance shall result in the denial of reinsurance, A&O subsidy, and risk subsidy on all underlying FCIC reinsured policies unless the underlying FCIC policy was sold by another AIP. If the underlying FCIC reinsured policy is sold by another AIP, the AIP that sold the NRS may be required to pay FCIC an amount equal to the reinsurance, A&O subsidy, and risk subsidy on the underlying FCIC policy.

(b) An electronic copy in Microsoft Office compatible format, of the new or revised NRS policy and related materials must be submitted at least 150 days prior to the first sales closing date applicable to the NRS policy. At a minimum, examples that demonstrate how liability and indemnities are calculated under differing scenarios must be included. Electronic copies of the NRS must be sent to the Deputy Administrator for Product Management (or successor) at *DeputyAdministrator@rma.usda.gov.*

(c) RMA will review the NRS policy. If any of the conditions found in paragraphs (c)(1) through (5) of this section are found to occur, FCIC will notify the AIP that submitted the NRS policy that if they sell the NRS policy, it will result in denial of reinsurance, A&O subsidy, and risk subsidy on all underlying FCIC reinsured policies, unless the underlying FCIC policy was sold by another AIP. If the underlying FCIC reinsured policy is sold by another AIP, the AIP that sold the NRS may be required to pay FCIC an amount equal to the reinsurance, A&O subsidy, and risk subsidy on the underlying FCIC policy.

(1) If the NRS policy materially increases or shifts risk to the underlying policy or plan of insurance reinsured by FCIC.

(i) An NRS policy will be considered to materially increase or shift risk to the underlying policy or plan of insurance reinsured by FCIC if RMA determines it:

(A) Creates a moral hazard, such as a financial incentive for the policyholder to behave in a way that increases the number or size of losses;

(B) Results in the underlying FCIC policy either triggering a loss sooner, or paying a larger indemnity than would otherwise be allowed by the terms and conditions of the underlying reinsured policy; or

(C) Allows for combined indemnities between the underlying FCIC reinsured policy and the NRS that are in excess of the value a producer would reasonably expect to receive for the insured commodity if a normal crop was produced and sold at a reasonable market price.

(ii) The NRS must include language that clearly states no indemnity will be paid in excess of the initial value of the insured commodity.

(2) The NRS reduces or limits the rights of the insured with respect to the underlying policy or plan of insurance reinsured by FCIC. An NRS policy will be considered to reduce or limit the rights of the insured with respect to the underlying policy or plan of insurance if RMA determines it affects, alters, preempts, or undermines the terms or conditions of the underlying policy or procedures issued by FCIC.

(3) The NRS disrupts the marketplace. An NRS policy will be considered to disrupt the marketplace if RMA determines it encourages planting more acres of the insured commodity in excess of normal market demand, adversely affects the sales or administration of reinsured policies, undermines producers' confidence in the Federal crop insurance program, or harms public perception of the Federal crop insurance program.

(4) The NRS is an impermissible rebate. An NRS may be considered to be an impermissible rebate if RMA determines that the premium rates charged are insufficient to cover the expected losses and a reasonable reserve or it offers other benefits that are generally provided at a cost.

(5) The NRS policy is conditioned upon or provides incentive for the purchase of the underlying policy or plan of insurance reinsured by FCIC with a specific agent or approved insurance provider.

(d) RMA will respond not less than 75 days before the first sales closing date or provide notice why RMA is unable to respond within the time frame allotted.

(e) NRS policies reviewed by RMA will need to be submitted once every five years unless a change is made to the NRS or the underlying policy. Once any changes are made to either policy, or the five year period has concluded, the NRS must be resubmitted for review.

Signed in Washington, DC, on August 2, 2016.

Timothy J. Gannon,

Acting Manager, Federal Crop Insurance Corporation.

[FR Doc. 2016–18743 Filed 8–11–16; 8:45 am]

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Part IV

Department of Justice

Drug Enforcement Administation

21 CFR Chapter II and Part 1301
Denial of Petition To Initiate Proceedings To Reschedule Marijuana; Proposed Rules and Applications To Become Registered Under the Controlled Substances Act To Manufacture Marijuana To Supply Researchers in the United States; Policy Statement

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Chapter II

[Docket No. DEA–426]

Denial of Petition To Initiate Proceedings To Reschedule Marijuana

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Denial of petition to initiate proceedings to reschedule marijuana.

SUMMARY: By letter dated July 19, 2016 the Drug Enforcement Administration (DEA) denied a petition to initiate rulemaking proceedings to reschedule marijuana. Because the DEA believes that this matter is of particular interest to members of the public, the agency is publishing below the letter sent to the petitioner which denied the petition, along with the supporting documentation that was attached to the letter.

DATES: August 12, 2016.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

July 19, 2016

Dear Ms. Raimondo and Mr. Inslee:

On November 30, 2011, your predecessors, The Honorable Lincoln D. Chafee and The Honorable Christine O. Gregoire, petitioned the Drug Enforcement Administration (DEA) to initiate rulemaking proceedings under the rescheduling provisions of the Controlled Substances Act (CSA). Specifically, your predecessors petitioned the DEA to have marijuana and "related items" removed from Schedule I of the CSA and rescheduled as medical cannabis in Schedule II.

Your predecessors requested that the DEA remove marijuana and related items from Schedule I based on their assertion that:

(1) Cannabis has accepted medical use in the United States;

(2) Cannabis is safe for use under medical supervision;

(3) Cannabis for medical purposes has a relatively low potential for abuse, especially in comparison with other Schedule II drugs.

In accordance with the CSA rescheduling provisions, after gathering the necessary data, the DEA requested a scientific and medical evaluation and scheduling recommendation from the Department of Health and Human Services (HHS). The HHS concluded that marijuana has a high potential for abuse, has no accepted medical use in the United States, and lacks an acceptable level of safety for use even under medical supervision. Therefore, the HHS recommended that marijuana remain in Schedule I. The scientific and medical evaluation and scheduling recommendation that the HHS submitted to the DEA is enclosed with this letter.

Based on the HHS evaluation and all other relevant data, the DEA has concluded that there is no substantial evidence that marijuana should be removed from Schedule I. A document prepared by the DEA addressing these materials in detail also is enclosed. In short, marijuana continues to meet the criteria for Schedule I control under the CSA because:

(1) *Marijuana has a high potential for abuse.* The HHS evaluation and the additional data gathered by the DEA show that marijuana has a high potential for abuse.

(2) *Marijuana has no currently accepted medical use in treatment in the United States.* Based on the established five-part test for making such determination, marijuana has no "currently accepted medical use" because: As detailed in the HHS evaluation, the drug's chemistry is not known and reproducible; there are no adequate safety studies; there are no adequate and well-controlled studies proving efficacy; the drug is not accepted by qualified experts; and the scientific evidence is not widely available.

(3) *Marijuana lacks accepted safety for use under medical supervision.* At present, there are no marijuana products approved by the U.S. Food and Drug Administration (FDA), nor is marijuana under a New Drug Application (NDA) evaluation at the FDA for any indication. The HHS evaluation states that marijuana does not have a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions. At this time, the known risks of marijuana use have not been shown to be outweighed by specific benefits in well-controlled clinical trials that scientifically evaluate safety and efficacy.

The statutory mandate of Title 21 United States Code, Section 812(b) (21 U.S.C. 812(b)) is dispositive. Congress established only one schedule, Schedule I, for drugs of abuse with "no currently accepted medical use in treatment in the United States" and "lack of accepted safety for use . . . under medical supervision." 21 U.S.C. 812(b).

Although the HHS evaluation and all other relevant data lead to the conclusion that marijuana must remain in schedule I, it should also be noted that, in view of United States obligations under international drug control treaties, marijuana cannot be placed in a schedule less restrictive than schedule II. This is explained in detail in accompanying document titled "Preliminary Note Regarding Treaty Considerations."

Accordingly, and as set forth in detail in the accompanying HHS and DEA documents, there is no statutory basis under the CSA for the DEA to grant your predecessors' petition to initiate rulemaking proceedings to reschedule marijuana. The petition is, therefore, hereby denied.

Sincerely,
Chuck Rosenberg,
Acting Administrator.
Attachments:

Preliminary Note Regarding Treaty Considerations

Cover Letter from HHS to DEA Summarizing the Scientific and Medical Evaluation and Scheduling Recommendation for Marijuana.

U.S. Department of Health and Human Services (HHS)—Basis for the Recommendation for Maintaining Marijuana in Schedule I of the Controlled Substances Act

U.S. Department of Justice—Drug Enforcement Administration (DEA), Schedule of Controlled Substances: Maintaining Marijuana in Schedule I of the Controlled Substances Act, Background, Data, and Analysis: Eight Factors Determinative of Control and Findings Pursuant to 21 U.S.C. 812(b)

Dated: July 19, 2016.

Chuck Rosenberg,
Acting Administrator, Preliminary Note Regarding Treaty Considerations.

As the Controlled Substances Act (CSA) recognizes, the United States is a party to the Single Convention on Narcotic Drugs, 1961 (referred to here as the Single Convention or the treaty). 21 U.S.C. 801(7). Parties to the Single Convention are obligated to maintain various control provisions related to the drugs that are covered by the treaty. Many of the provisions of the CSA were enacted by Congress for the specific purpose of ensuring U.S. compliance with the treaty. Among these is a scheduling provision, 21 U.S.C. 811(d)(1). Section 811(d)(1) provides that, where a drug is subject to control under the Single Convention, the DEA Administrator (by delegation from the Attorney General) must "issue an order controlling such drug under the schedule he deems most appropriate to carry out such [treaty] obligations, without regard to the findings required by [21 U.S.C. 811(a) or 812(b)] and without regard to the procedures prescribed by [21 U.S.C. 811(a) and (b)]."

Marijuana is a drug listed in the Single Convention. The Single Convention uses the term "cannabis" to refer to marijuana.[1] Thus, the DEA

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[1] Under the Single Convention, "cannabis plant' means any plant of the genus *Cannabis.*" Article 1(c). The Single Convention defines "cannabis" to include "the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated." Article 1(b). This definition of "cannabis" under the Single Convention is slightly less inclusive than the CSA definition of "marihuana," which includes all parts of the cannabis plant except for the mature stalks, sterilized seeds, oil from the seeds, and certain derivatives thereof. *See* 21 U.S.C. 802(16). Cannabis and cannabis resin are included in the list of drugs in Schedule I and Schedule IV of the Single Convention. In contrast to the CSA, the drugs listed in Schedule IV of the Single Convention are also

Administrator is obligated under section 811(d) to control marijuana in the schedule that he deems most appropriate to carry out the U.S. obligations under the Single Convention. It has been established in prior marijuana rescheduling proceedings that placement of marijuana in either schedule I or schedule II of the CSA is "necessary as well as sufficient to satisfy our international obligations" under the Single Convention. *NORML* v. *DEA,* 559 F.2d 735, 751 (D.C. Cir. 1977). As the United States Court of Appeals for the DC Circuit has stated, "several requirements imposed by the Single Convention would not be met if cannabis and cannabis resin were placed in CSA schedule III, IV, or V."[2] *Id.* Therefore, in accordance with section 811(d)(1), DEA must place marijuana in either schedule I or schedule II.

Because schedules I and II are the only possible schedules in which marijuana may be placed, for purposes of evaluating this scheduling petition, it is essential to understand the differences between the criteria for placement of a substance in schedule I and those for placement in schedule II. These criteria are set forth in 21 U.S.C. 812(b)(1) and (b)(2), respectively. As indicated therein, substances in both schedule I and schedule II share the characteristic of "a high potential for abuse." Where the distinction lies is that schedule I drugs have "no currently accepted medical use in treatment in the United States" and "a lack of accepted safety for use of the drug . . . under medical supervision," while schedule II drugs do have "a currently accepted medical use in treatment in the United States."[3]

Accordingly, in view of section 811(d)(1), this scheduling petition turns on whether marijuana has a currently accepted medical use in treatment in the United States. If it does not, DEA must, pursuant to section 811(d), deny the petition and keep marijuana in schedule I.

As indicated, where section 811(d)(1) applies to a drug that is the subject of a rescheduling petition, the DEA Administrator must issue an order controlling the drug under the schedule he deems most appropriate to carry out United States obligations under the Single Convention, without regard to the findings required by sections 811(a) or 812(b) and without regard to the procedures prescribed by sections 811(a) and (b). Thus, since the only determinative issue in evaluating the present scheduling petition is whether marijuana has a currently accepted medical use in treatment in the United States, DEA need not consider the findings of sections 811(a) or 812(b) that have no bearing on that determination, and DEA likewise need not follow the procedures prescribed by sections 811(a) and (b) with respect to such irrelevant findings. Specifically, DEA need not evaluate the relative abuse potential of marijuana or the relative extent to which abuse of marijuana may lead to physical or psychological dependence.

As explained below, the medical and scientific evaluation and scheduling recommendation issued by the Secretary of Health and Human Services concludes that marijuana has no currently accepted medical use in treatment in the United States, and the DEA Administrator likewise so concludes. For the reasons just indicated, no further analysis beyond this consideration is required. Nonetheless, because of the widespread public interest in understanding all the facts relating to the harms associated with marijuana, DEA is publishing here the entire medical and scientific analysis and scheduling evaluation issued by the Secretary, as well as DEA's additional analysis.

Department of Health and Human Services,
Office of the Secretary Assistant Secretary for Health, Office of Public Health and Science, Washington, DC 20201.

June 25, 2015.

The Honorable Chuck Rosenberg

Acting Administrator, Drug Enforcement Administration, U.S. Department of Justice, 8701 Morrissette Drive, Springfield, VA 22152.

Dear Mr. Rosenberg:

Pursuant to the Controlled Substances Act (CSA, 21 U.S.C. § 811(b), (c), and (f)), the Department of Health and Human Services (HHS) is recommending that marijuana continue to be maintained in Schedule I of the CSA.

The Food and Drug Administration (FDA) has considered the abuse potential and dependence-producing characteristics of marijuana.

Marijuana meets the three criteria for placing a substance in Schedule I of the CSA under 21 U.S.C. 812(b)(1). As discussed in the enclosed analyses, marijuana has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Accordingly, HHS recommends that marijuana be maintained in Schedule I of the CSA. Enclosed are two documents prepared by FDA's Controlled Substance Staff (in response to petitions filed in 2009 by Mr. Bryan Krumm and in 2011 by Governors Lincoln D. Chafee and Christine O. Gregoire) that form the basis for the recommendation. Pursuant to the requests in the petitions, FDA broadly evaluated marijuana, and did not focus its evaluation on particular strains of marijuana or components or derivatives of marijuana.

FDA's Center for Drug Evaluation and Research's current review of the available evidence and the published clinical studies on marijuana demonstrated that since our 2006 scientific and medical evaluation and scheduling recommendation responding to a previous DEA petition, research with marijuana has progressed. However, the available evidence is not sufficient to determine that marijuana has an accepted medical use. Therefore, more research is needed into marijuana's effects, including potential medical uses for marijuana and its derivatives. Based on the current review, we identified several methodological challenges in the marijuana studies published in the literature. We recommend they be addressed in future clinical studies with marijuana to ensure that valid scientific data are generated in studies evaluating marijuana's safety and efficacy for therapeutic use. For example, we recommend that studies need to focus on consistent administration and reproducible dosing of marijuana, potentially through the use of administration methods other than smoking. A summary of our review of the published literature on the clinical uses of marijuana, including recommendations for future studies, is attached to this document.

FDA and the National Institutes of Health's National Institute on Drug Abuse (NIDA) also believe that work continues to be needed to ensure support by the federal government for the efficient conduct of clinical research using marijuana. Concerns have been raised about whether the existing federal regulatory system is flexible enough to respond to increased interest in research into the potential therapeutic uses of marijuana and marijuana-derived drugs. HHS welcomes an opportunity to continue to explore these concerns with DEA.

Should you have any questions regarding theses recommendations, please contact Corinne P. Moody, Science Policy Analyst, Controlled Substances Staff, Center for Drug Evaluation and Research, FDA, at (301) 796–3152.

Sincerely yours,

Karen B. DeSalvo, MD, MPH, MSc

Acting Assistant Secretary for Health.

Enclosure: Basis for the Recommendation for Maintaining Marijuana in Schedule I of the Controlled Substances Act

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listed in Schedule I of the Single Convention and are subject to the same controls as Schedule I drugs as well as additional controls. Article 2, par. 5

[2] The Court further stated: "For example, [article 31 paragraph 4 of the Single Convention] requires import and export permits that would not be obtained if the substances were placed in CSA schedules III through V. In addition, the quota and [recordkeeping] requirements of Articles 19 through 21 of the Single Convention would be satisfied only by placing the substances in CSA schedule I or II." *Id.* n. 71 (internal citations omitted).

[3] As DEA has stated in evaluating prior marijuana rescheduling petitions, "Congress established only one schedule, schedule I, for drugs of abuse with 'no currently accepted medical use in treatment in the United States'and 'lack of accepted safety for use . . . under medical supervision.' 21 U.S.C. 812(b)." 76 FR 40552 (2011); 66 FR 20038 (2001).

Basis for the Recommendation for Maintaining Marijuana in Schedule I of the Controlled Substances Act

On November 30, 2011, Governors Lincoln D. Chafee of Rhode Island and Christine O. Gregoire of Washington submitted a petition to the Drug Enforcement Administration (DEA) requesting that proceeding be initiated to repeal the rules and regulations that place marijuana[4] in Schedule I of the Controlled Substances Act (CSA). The petition contends that cannabis has an accepted medical use in the United States, is safe for use under medical supervision, and has a relatively low abuse potential compared to other Schedule II drugs. The petition requests that marijuana and ''related items'' be rescheduled in Schedule II of the CSA. In June 2013, the DEA Administrator requested that the U.S. Department of Health and Human Services (HHS) provide a scientific and medical evaluation of the available information and a scheduling recommendation for marijuana, in accordance with the provisions of 21 U.S.C. 811(b).

In accordance with 21 U.S.C. 811(b), DEA has gathered information related to the control of marijuana (*Cannabis sativa*)[5] under the CSA. Pursuant to 21 U.S.C. 811(b), the Secretary of HHS is required to consider in a scientific and medical evaluation eight factors determinative of control under the CSA. Following consideration of the eight factors, if it is appropriate, the Secretary must make three findings to recommend scheduling a substance in the CSA. The findings relate to a substance's abuse potential, legitimate medical use, and safety or dependence liability.

Administrative responsibilities for evaluating a substance for control under the CSA are performed by the Food and Drug Administration (FDA), with the concurrence of the National Institute on Drug Abuse (NIDA), as described in the Memorandum of Understanding (MOU) of March 8, 1985 (50 FR 9518–20).

In this document, FDA recommends the continued control of marijuana in Schedule I of the CSA. Pursuant to 21 U.S.C. 811(c), the eight factors pertaining to the scheduling of marijuana are considered below.

1. Its Actual or Relative Potential for Abuse

Under the first factor the Secretary must consider marijuana's actual or relative potential for abuse. The CSA does not define the term ''abuse.'' However, the CSA's legislative history suggests the following in determining whether a particular drug or substance has a potential for abuse:[6]

a. There is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community.

b. There is a significant diversion of the drug or drugs containing such a substance from legitimate drug channels.

c. Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice.

d. The drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

In the development of this scientific and medical evaluation for the purpose of scheduling, the Secretary analyzed considerable data related to the substance's abuse potential. The data include a discussion of the prevalence and frequency of use, the amount of the substance available for illicit use, the ease of obtaining or manufacturing the substance, the reputation or status of the substance ''on the street,'' and evidence relevant to at-risk populations. Importantly, the petitioners define marijuana as including all *Cannabis* cultivated strains. Different marijuana samples derived from various cultivated strains may have very different chemical constituents, thus the analysis is based on what is known about the range of these constituents across all cultivated strains.

Determining the abuse potential of a substance is complex with many dimensions, and no single test or assessment provides a complete characterization. Thus, no single measure of abuse potential is ideal. Scientifically, a comprehensive evaluation of the relative abuse potential of a substance can include consideration of the following elements: Receptor binding affinity, preclinical pharmacology, reinforcing effects, discriminative stimulus effects, dependence producing potential, pharmacokinetics, route of administration, toxicity, data on actual abuse, clinical abuse potential studies, and public health risks. Importantly, abuse can exist independently from tolerance or physical dependence because individuals may abuse drugs in doses or patterns that do not induce these phenomena. Additionally evidence of clandestine population and illicit trafficking of a substance can shed light on both the demand for a substance as well as the ease of obtaining a substance. Animal and human laboratory data and epidemiological data are all used in determining a substance's abuse potential. Moreover, epidemiological data can indicate actual abuse.

The petitioners compare the effects of marijuana to currently controlled Schedule II substances and make repeated claims about their comparative effects. Comparisons between marijuana and the diverse array of Schedule II substances is difficult, because of the pharmacologically dissimilar actions of substances of Schedule II of the CSA. For example, Schedule II substances include stimulant-like drugs (*e.g.*, cocaine, methylphenidate, and amphetamine), opioids (*e.g.*, oxycodone, fentanyl), sedatives (*e.g.*, pentobarbital, amobarbital), dissociative anesthetics (*e.g.*, PCP), and naturally occurring plant components (*e.g.*, coca leaves and poppy straw). The mechanism(s) of action of the above Schedule II substances are wholly different from one another, and they are different from tetrahydrocannabinol (THC) and marijuana as well. For example, Schedule II stimulants typically function by increasing monoaminergic tone via an increase in dopamine and norepinephrine (Schmitt et al., 2013). In contrast, opioid analgesics function via mu-opioid receptor agonist effects. These differing mechanism(s) of action result in vastly different behavioral and adverse effect profiles, making comparisons across the range of pharmacologically diverse C–II substances inappropriate.

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[4] Note that ''marihuana'' is the spelling originally used in the Controlled Substances Act (CSA). This document uses the spelling that is more common in current usage, ''marijuana.''

[5] The CSA defines marijuana as the following:

All parts of the plant Cannabis Sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination (21 U.S.C. 802(16)).

[6] Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91–1444, 91st Cong., Sess. 1 (1970) reprinted in U.S.C.C.A.N. 4566, 4603.

In addition, many substances scheduled under the CSA are reviewed and evaluated within the context of commercial drug development, using data submitted in the form of a new drug application (NDA). A new analgesic drug might be compared to a currently scheduled analgesic drug as part of the assessment of its relative abuse potential. However, because the petitioners have not identified a specific indication for the use of marijuana, identifying an appropriate comparator based on indication cannot be done.

a. There is evidence that individuals are taking the substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community.

Evidence shows that some individuals are taking marijuana in amounts sufficient to create a hazard to their health and to the safety of other individuals and the community. A large number of individuals use marijuana. HHS provides data on the extent of marijuana abuse through NIDA and the Substance Abuse and Mental Health Services Administration (SAMHSA). According to the most recent data from SAMHSA's 2012 National Survey on Drug Use and Health (NSDUH), which estimates the number of individuals who have used a substance within a month prior to the study (described as "current use"), marijuana is the most commonly used illicit drug among Americans aged 12 years and older, with an estimated 18.9 million Americans having used marijuana within the month prior to the 2012 NSDUH. Compared to 2004, when an estimated 14.6 million individuals reported using marijuana within the month prior to the study, the estimated rates in 2012 show an increase of approximately 4.3 million individuals. The 2013 Monitoring the Future (MTF) survey of 8th, 10th, and 12th grade students also indicates that marijuana is the most widely used illicit substance in this age group. Specifically, current month use was at 7.0 percent of 8th graders, 18.0 percent of 10th, graders and 22.7 percent of 12th graders. Additionally, the 2011 Treatment Episode Data Set (TEDS) reported that primary marijuana abuse accounted for 18.1 percent of non-private substance-abuse treatment facility admissions, with 24.3 percent of those admitted reporting daily use. However, of these admissions for primary marijuana abuse, the criminal justice system referred 51.6 percent to treatment. SAMHSA's Drug Abuse Warning Network (DAWN) was a national probability survey of U.S. hospitals with emergency departments (EDs) and was designed to obtain information on ED visits in which marijuana was mentioned, accounting for 36.4 percent of illicit drug related ED visits. There are some limitations related to DAWN data on ED visits, which are discussed in detail in Factor 4, "Its History and Current Pattern of Abuse;" Factor 5, "The Scope, Duration, and Significance of Abuse;" and Factor 6, "What, if any, Risk There is to the Public Health." These factors contain detailed discussions of these data.

A number of risks can occur with both acute and chronic use of marijuana. Detailed discussions of the risks are addressed in Factor 2, "Scientific Evidence of its Pharmacological Effect, if Known," and Factor 6, "What, if any, Risk There is to the Public Health."

b. There is significant diversion of the substance from legitimate drug channels.

There is a lack of evidence of significant diversion of marijuana from legitimate drug channels, but this is likely due to the fact that marijuana is more widely available from illicit sources rather than through legitimate channels. Marijuana is not an FDA-approved drug product, as an NDA or biologics license application (BLA) has not been approved for marketing in the United States. Numerous states and the District of Columbia have state-level medical marijuana laws that allow for marijuana use within that state. These state-level drug channels do not have sufficient collection of data related to medical treatment, including efficacy and safety.

Marijuana is used by researchers for nonclinical research as well as clinical research under investigational new drug (IND) applications; this represents the only legitimate drug channel in the United States. However, marijuana used for research represents a very small contribution of the total amount of marijuana available in the United States, and thus provides limited information about diversion. In addition, the lack of significant diversion of investigation supplies is likely because of the widespread availability of illicit marijuana of equal or greater amounts of delta^{9}-THC. The data originating from the DEA on seizure statistics demonstrate the magnitude of the availability for illicit marijuana. DEA's System to Retrieve Information from Drug Evidence (STRIDE) provides information on total domestic drug seizures. STRIDE reports a total domestic seizure of 573,195 kg of marijuana in 2011, the most recent year with complete data that is currently publically available (DEA Domestic Drug Seizures, n.d.).

c. Individuals are taking the substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such substances.

Because the FDA has not approved an NDA or BLA for a marijuana drug product for any therapeutic indication, the only way an individual can take marijuana on the basis of medical advice through legitimate channels at the federal level is by participating in research under an IND application. That said, numerous states and the District of Columbia have passed state-level medical marijuana laws allowing for individuals to use marijuana under certain circumstances. However, data are not yet available to determine the number of individuals using marijuana under these state-level medical marijuana laws. Regardless, according to the 2012 NSDUH data, 18.9 million American adults currently use marijuana (SAMHSA, 2013). Based on the large number of individuals reporting current use of marijuana and the lack of an FDA-approved drug product in the United States, one can assume that it is likely that the majority of individuals using marijuana do so on their own initiative rather than on the basis of medical advice from a licensed practitioner.

d. The substance is so related in its action to a substance already listed as having a potential for abuse to make it likely that it will have the same potential for abuse as such substance, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

FDA has approved two drug products containing cannabinoid compounds that are structurally related to the active components in marijuana. These two marketed products are controlled under the CSA. Once a specific drug product containing cannabinoids becomes approved, that specific drug product may be moved from Schedule I to a different Schedule (II–V) under the CSA. Firstly, Marinol—generically known as dronabinol—is a Schedule III drug product containing synthetic delta^{9}-THC. Marinol, which is formulated in sesame oil in soft gelatin capsules, was first placed in Schedule II under the CSA following its approval by the FDA. Marinol was later rescheduled to Schedule III under the CSA because of low numbers of reports of abuse relative to marijuana. Dronabinol is listed in Schedule I under the CSA. FDA approved Marinol in 1985 for the treatment of nausea and vomiting associated with cancer chemotherapy in patients who failed to respond adequately to conventional anti-emetic treatments. In 1992, FDA approved Marional for anorexia associated with weight loss in patients with acquired immunodeficiency syndrome (AIDS). Secondly, in 1985, FDA approved Cesamet, a drug product containing the Schedule II substance nabilone, for the treatment of nausea and vomiting associated with cancer chemotherapy. Besides the two cannabinoid-containing drug products FDA approved for marketing, other naturally occurring cannabinoids and their derivatives (from *Cannabis*) and their synthetic equivalents with similar chemical structure and pharmacological activity are included in the CSA as Schedule I substances.

2. Scientific Evidence of Its Pharmacological Effects, if Known

Under the second factor, the Secretary must consider the scientific evidence of marijuana's pharmacological effects. Abundant scientific data are available on the neurochemistry, toxicology, and pharmacology of marijuana. This section includes a scientific evaluation of marijuana's neurochemistry; pharmacology; and human and animal behavioral, central nervous system, cognitive, cardiovascular, autonomic, endocrinological, and immunological system effects. The overview presented below relies upon the most current research literature on cannabinoids.

Neurochemistry and Pharmacology of Marijuana

Marijuana is a plant that contains numerous natural constituents, such as cannabinoids, that have a variety of pharmacological actions. The petition defines marijuana as including all *Cannabis* cultivated strains. Different marijuana samples derived from various cultivated strains may have very different chemical constituents including delta^9-THC and other cannabinoids (Appendino et al., 2011). As a consequence, marijuana products from different strains will have different biological and pharmacological profiles.

According to ElSohly and Slade (2005) and Appendino et al. (2011), marijuana contains approximately 525 identified natural constituents, including approximately 100 compounds classified as cannabinoids. Cannabinoids primarily exist in *Cannabis,* and published data suggests that most major cannabinoid compounds occurring naturally have been identified chemically. New and minor cannabinoids and other new compounds are continuously being characterized (Pollastro et al., 2011). So far, only two cannabinoids (cannabigerol and its corresponding acid) have been obtained from a non-*Cannabis* source. A South African *Helichrysum* (*H. umbraculigerum*) accumulates these compounds (Appendino et al., 2011). The chemistry of marijuana is described in more detail in Factor 3, "The State of Current Scientific Knowledge Regarding the Drug or Other Substance."

The site of cannabinoid action is at the cannabinoid receptors. Cloning of cannabinoid receptors, first from rat brain tissue (Matsuda et al., 1990) and then from human brain tissue (Gerard et al., 1991), has verified the site of action. Two cannabinoid receptors, CB_1 and CB_2, were characterized (Battista et al., 2012; Piomelli, 2005). Evidence of a third cannabinoid receptor exists, but it has not been identified (Battista et al., 2012).

The cannabinoid receptors, CB_1 and CB_2, belong to the family of G-protein-coupled receptors, and present a typical seven transmembrane-spanning domain structure. Cannabinoid receptors link to an inhibitory G-protein (G_i), such that adenylate cyclase activity is inhibited when a ligand binds to the receptor. This, in turn, prevents the conversion of ATP to the second messenger, cyclic AMP (cAMP). Examples of inhibitory coupled receptors include opioid, muscarinic cholinergic, alpha$_2$-adrenoreceptors, dopamine (D_2), and serotonin (5-HT_1).

Cannabinoid receptor activation inhibits N- and P/Q-type calcium channels and activates inwardly rectifying potassium channels (Mackie et al., 1995; Twitchell et al., 1997). N-type calcium channel inhibition decreases neurotransmitter release from several tissues. Thus, calcium channel inhibition may be the mechanism by which cannabinoids inhibit acetylcholine, norepinephrine, and glutamate release from specific areas of the brain. These effects may represent a potential cellular mechanism underlying cannabinoids' antinociceptive and psychoactive effects (Ameri, 1999).

CB_1 receptors are found primarily in the central nervous system, but are also present in peripheral tissues. CB_1 receptors are located mainly in the basal ganglia, hippocampus, and cerebellum of the brain (Howlett et al., 2004). The localization of these receptors may explain cannabinoid interference with movement coordination and effects on memory and cognition. Additionally, CB_1 receptors are found in the immune system and numerous other peripheral tissues (Petrocellis and Di Marzo, 2009). However, the concentration of CB_1 receptors is considerably lower in peripheral tissues than in the central nervous system (Herkenharn et al., 1990 and 1992).

CB_2 receptors are found primarily in the immune system, but are also present in the central nervous system and other peripheral tissues. In the immune system, CB_2 receptors are found predominantly in B lymphocytes and natural killer cells (Bouaboula et al., 1993). CB_2 receptors may mediate cannabinoids' immunological effects (Galiegue et al., 1995). Additionally, CB_2 receptors have been localized in the brain, primarily in the cerebellum and hippocampus (Gong et al., 2006). The distribution of CB_2 receptors throughout the body is less extensive than the distribution of CB_1 receptors (Petrocellis and Di Marzo, 2009). However, both CB_1 and CB_2 receptors are present in numerous tissues of the body.

Cannabinoid receptors have endogenous ligands. In 1992 and 1995, two endogenous cannabinoid receptor agonists, anandamide and arachidonyl glycerol (2-AG), respectively, were identified (Di Marzo, 2006). Anandamide is a low efficacy agonist (Breivogel and Childers, 2000) and 2-AG is a high efficacy agonist (Gonsiorek et al., 2000). Cannabinoid endogenous ligands are present in central as well as peripheral tissues. A combination of uptake and hydrolysis terminate the action of the endogenous ligands. The endogenous cannabinoid system is a locally active signaling system that, to help restore homeostasis, is activated "on demand" in response to changes to the local homeostasis (Petrocellis and Di Marzo, 2009). The endogenous cannabinoid system, including the endogenous cannabinoids and the cannabinoid receptors, demonstrate substantial plasticity in response to several physiological and pathological stimuli (Petrocellis and Di Marzo, 2009). This plasticity is particularly evident in the central nervous system.

Delta^9-THC and cannabidiol (CBD) are two abundant cannabinoids present in marijuana. Marijuana's major psychoactive cannabinoid is delta^9-THC (Wachtel et al., 2002). In 1964, Gaoni and Mechoularn first described delta^9-THC's structure and function. In 1963, Mechoularn and Shvo first described CBD's structure. The pharmacological actions of CBD have not been fully studied in humans.

Delta^9-THC and CBD have varying affinity and effects at the cannabinoid receptors. Delta^9-THC displays similar affinity for CB_1 and CB_2 receptors, but behaves as a weak agonist for CB_2 receptors. The identification of synthetic cannabinoid ligands that selectively bind to CB_2 receptors but do not have the typical delta^9-THC-like psychoactive properties suggests that the activation of CB_1-receptors mediates cannabinoids' psychotropic effects (Hanus et al., 1999). CBD has low affinity for both CB_1 and CB_2 receptors (Mechoulam et al., 2007). According to Mechoulam et al. (2007), CBD has antagonistic effects at CB_1 receptors and some inverse agonistic properties at CB_2 receptors. When cannabinoids are given subacutely to rats, CB_1 receptors down-regulate and the binding of the second messenger system coupled to CB_1 receptors, GTPgarnmaS, decreases (Breivogel et al., 2001).

Animal Behavioral Effects

Self-Administration

Self-administration is a method that assesses the ability of a drug to produce rewarding effects. The presence of rewarding effects increases the likelihood of behavioral responses to obtain additional drug. Animal self-administration of a drug is often useful in predicting rewarding effects in humans, and is indicative of abuse liability. A good correlation is often observed between those drugs that rhesus monkeys self-administer and those drugs that humans abuse (Balster and Bigelow, 2003). Initially, researchers could not establish self-administration of cannabinoids, including delta^9-THC, in animal models. However, self-administration of delta^9-THC can now be established in a variety of animal models under specific training paradigms (Justinova et al., 2003, 2004, 2005).

Squirrel monkeys, with and without prior exposure to other drugs of abuse, self-administer delta^9-THC under specific conditions. For instance, Tanda et al. (2000) observed that when squirrel monkeys are initially trained to self-administer intravenous cocaine, they will continue to bar-press delta^9-THC at the same rate as they would with cocaine. The doses were notably comparable to those doses used by humans who smoke marijuana. SR141716, a CB_1 cannabinoid receptor agonist-antagonist, can block this rewarding effect. Other studies show that naïve squirrel monkeys can be successfully trained to self-administer delta^9-THC intravenously (Justinova et al., 2003). The maximal responding rate is 4 µg/kg per injection, which is 2–3 times greater than observed in previous studies using cocaine-experienced monkeys. Naltrexone, a mu-opioid antagonist, partially antagonizes these rewarding effects of delta^9-THC (Justinova et al., 2004).

Additionally, data demonstrate that under specific conditions, rodents self-administer cannabinoids. Rats will self-administer delta^9-THC when applied intracerebroventricularly (i.c.v.), but only at the lowest doses tested (0.01–0.02 µg/infusion) (Braida et al., 2004). SR141716 and the opioid antagonist naloxone can antagonize this effect. However, most studies involve rodents self-administrating the synthetic cannabinoid WIN 55212, a CB_1 receptor agonist with a non-cannabinoid structure (Deiana et al., 2007; Fattore et al., 2007; Martellotta et al., 1998; Mendizabal et al., 2006).

Aversive effects, rather than reinforcing effects, occur in rats that received high doses of WIN 55212 (Chaperon et al., 1998) or delta^9-THC (Sanudo-Pena et al., 1997), indicating a possible critical dose-dependent effect. In both studies, SR141716 reversed these aversive effects.

Conditioned Place Preference

Conditioned place preference (CPP) is a less rigorous method than self-administration for determining whether or not a drug has rewarding properties. In this behavioral test, animals spend time in two distinct environments: one where they previously received a drug and one where they received a placebo. If the drug is reinforcing, animals will choose to spend more time in the environment paired with the drug, rather than with the placebo, when presented with both options simultaneously.

Animals show CPP to delta^9-THC, but only at the lowest doses tested (0.075–1.0 mg/kg, intraperitoneal (i.p.)) (Braida et al., 2004). SR141716 and naloxone antagonize this effect (Braida et al., 2004). As a partial agonist, SR141716 can induce CPP at doses of 0.25, 0.5, 2 and 3 mg/kg (Cheer et al., 2000). In knockout mice, those without µ-opioid receptors do not develop CPP to delta^9-THC (Ghozland et al., 2002).

Drug Discrimination Studies

Drug discrimination is a method where animals indicate whether a test drug produces physical or psychic perceptions similar to those produced by a known drug of abuse. In this test, an animal learns to press one bar when it receives the known drug of abuse and another bar when it receives placebo. To determine whether the test drug is like the known drug of abuse, a challenge session with the test drug demonstrates which of the two bars the animal presses more often.

In addition to humans (Lile et al., 2009; Lile et al., 2011), it has been noted that animals, including monkeys (McMahon, 2009), mice (McMahon et al., 2008), and rats (Gold et al., 1992), are able to discriminate cannabinoids from other drugs or placebo. Moreover, the major active metabolite of delta^9-THC, 11-hydroxy-delta^9-THC, also generalizes (following oral administration) to the stimulus cues elicited by delta^9-THC (Browne and Weissman, 1981). Twenty-two other cannabinoids found in marijuana also fully substitute for delta^9-THC. However, CBD does not substitute for delta^9-THC in rats (Vann et al., 2008).

Discriminative stimulus effects of delta^9-THC are pharmacologically specific for marijuana containing cannabinoids (Balster and Prescott, 1992; Browne and Weissman, 1981; Wiley et al., 1993, 1995). The discriminative stimulus effects of the cannabinoid group appear to provide unique effects because stimulants, hallucinogens, opioids, benzodiazepines, barbiturates, NMDA antagonists, and antipsychotics do not fully substitute for delta^9-THC.

Central Nervous System Effects

Human Physiological and Psychological Effects

Psychoactive Effects

Below is a list of the common subjective responses to cannabinoids (Adams and Martin, 1996; Gonzalez, 2007; Hollister 1986, 1988; Institute of Medicine, 1982). According to Maldonado (2002), these responses to marijuana are pleasurable to many humans and are often associated with drug-seeking and drug-taking. High levels of positive psychoactive effects are associated with increased marijuana use, abuse, and dependence (Scherrer et al., 2009; Zeiger et al., 2010).

(1) Disinhibition, relaxation, increased sociability, and talkativeness.

(2) Increased merriment and appetite, and even exhilaration at high doses.

(3) Enhanced sensory perception, which can generate an increased appreciation of music, art, and touch.

(4) Heightened imagination, which can lead to a subjective sense of increased creativity.

(5) Initial dizziness, nausea, tachycardia, facial flushing, dry mouth, and tremor.

(6) Disorganized thinking, inability to converse logically, time distortions, and short-term memory impairment.

(7) Ataxia and impaired judgment, which can impede driving ability or

lead to an increase in risk-tasking behavior.

(8) Illusions, delusions, and hallucinations that intensify with higher doses.

(9) Emotional lability, incongruity of affect, dysphoria, agitation, paranoia, confusion, drowsiness, and panic attacks, which are more common in inexperienced or high-dosed users.

As with many psychoactive drugs, a person's medical, psychiatric, and drug-taking history can influence the individual's response to marijuana. Dose preferences to marijuana occur in that marijuana users prefer higher concentrations of the principal psychoactive substance (1.95 percent delta^9-THC) over lower concentrations (0.63 percent delta^9-THC) (Chait and Burke, 1994). Nonetheless, frequent marijuana users (>100 times of use) were able to identify a drug effect from low-dose delta^9-THC better than occasional users (<10 times of use) while also experiencing fewer sedative effects from marijuana (Kirk and de Wit, 1999).

The petitioners contend that many of marijuana's naturally occurring cannabinoids mitigate the psychoactive effects of delta^9-THC, and therefore that marijuana lacks sufficient abuse potential to warrant Schedule I placement, because Marinol, which is in Schedule III, contains only delta^9-THC. This theory has not been demonstrated in controlled studies. Moreover, the concept of abuse potential encompasses all properties of a substance, including its chemistry, pharmacology, and pharmacokinetics, as well as usage patterns and diversion history. The abuse potential of a substance is associated with the repeated or sporadic use of a substance in nonmedical situations for the psychoactive effects the substance produces. These psychoactive effects include euphoria, perceptual and other cognitive distortions, hallucinations, and mood changes. However, as stated above, the abuse potential not only includes the psychoactive effects, but also includes other aspects related to a substance.

DEA's final published rule entitled "Rescheduling of the Food and Drug Administration Approved Product Containing Synthetic Dronabinol [(−)-delta^9-(trans)-Tetrahydrocannabinol] in Sesame Oil and Encapsulated in Soft Gelatin Capsules From Schedule II to Schedule III" (64 FR 35928, July 2, 1999) rescheduled Marinol from Schedule II to Schedule III. The HHS assessment of the abuse potential and subsequent scheduling recommendation compared Marinol to marijuana on different aspects related to abuse potential. Major differences in formulation, availability, and usage between marijuana and the drug product, Marinol, contribute to their differing abuse potentials.

Hollister and Gillespie (1973) estimated that delta^9-THC by smoking is 2.6 to 3 times more potent than delta^9-THC ingested orally. The intense psychoactive drug effect achieved, rapidly by smoking is generally considered to produce the effect desired by the abuser. This effect explains why abusers often prefer to administer certain drugs by inhalation, intravenously, or intranasally rather than orally. Such is the case with cocaine, opium, heroin, phencyclidine, methamphetamine, and delta^9-THC from marijuana (0.1–9.5 percent delta^9-THC range) or hashish (10–30 percent delta^9-THC range) (Wesson and Washburn, 1990). Thus, the delayed onset and longer duration of action for Marinol may be contributing factors limiting the abuse or appeal of Marinol as a drug of abuse relative to marijuana.

The formulation of Marinol is a factor that contributes to differential scheduling of Marinol and marijuana. For example, extraction and purification of dronabinol from the encapsulated sesame oil mixture of Marinol is highly complex and difficult. Additionally, the presence of sesame oil mixture in the formulation may preclude the smoking of Marinol-laced cigarettes.

Additionally, there is a dramatic difference between actual abuse and illicit trafficking of Marinol and marijuana. Despite Marinol's availability in the United States, there have been no significant reports of abuse, diversion, or public health problems due to Marinol. By comparison, 18.9 million American adults report currently using marijuana (SAMHSA, 2013).

In addition, FDA's approval of an NDA for Marinol allowed for Marinol to be rescheduled to Schedule II, and subsequently to Schedule III of the CSA. In conclusion, marijuana and Marinol differ on a wide variety of factors that contribute to each substance's abuse potential. These differences are major reasons distinguishing the higher abuse potential for marijuana and the different scheduling determinations of marijuana and Marinol.

In terms of the petitioners' claim that different cannabinoids present in marijuana mitigate the psychoactive effects of delta^9-THC, only three of the cannabinoids present in marijuana were simultaneously administered with delta^9-THC to examine how the combinations of these cannabinoids such as CBD, cannabichromene (CBC) and cannabinol (CBN) influence delta^9-THC's psychoactive effects. Dalton et al. (1976) observed that smoked administration of placebo marijuana cigarettes containing injections of 0.15 mg/kg CBD combined with 0.025mg/kg of delta^9-THC, in a 7:1 ratio of CBD to delta^9-THC, significantly decreased ratings of acute subjective effects and "high" when compared to smoking delta^9-THC alone. In contrast, Ilan et al. (2005) calculated the naturally occurring concentrations of CBC and CBD in a batch of marijuana cigarettes with either 1.8 percent or 3.6 percent delta^9-THC concentration by weight. For each strength of delta^9-THC in marijuana cigarettes, the concentrations of CBC and CBD were classified in groups of either low or high. The study varied the amount of CBC and CBD within each strength of delta^9-THC marijuana cigarettes, with administrations consisting of either low CBC (between 0.1–0.2 percent CBC concentration by weight) and low CBD (between 0.1–0.4 percent CBD concentration by weight), high CBC (>0.5 percent CBC concentration by weight) and low CBD, or low CBC and high CBD (>1.0 percent CBD concentration by weight). Overall, all combinations scored significantly greater than placebo on ratings of subjective effects, and there was no significant difference between any combinations.

The oral administration of a combination of either 15, 30, or 60 mg CBD with 30 mg delta^9-THC dissolved in liquid (in a ratio of at least 1:2 CBD to delta^9-THC) reduced the subjective effects produced by delta^9-THC alone (Karniol et al., 1974). Additionally, orally administering a liquid mixture combining 1 mg/kg CBD with 0.5 mg/kg of delta^9-THC (ratio of 2:1 CBD to delta^9-THC) decreased scores of anxiety and marijuana drug effect on the Addiction Research Center Inventory (ARCI) compared to delta^9-THC alone (Zuardi et al.,1982). Lastly, oral administration of either 12.5, 25, or 50 mg CBN combined with 25 mg delta^9-THC dissolved in liquid (ratio of at least 1:2 CBN to delta^9-THC) significantly increased subjective ratings of "drugged," "drowsy," "dizzy," and "drunk," compared to delta^9-THC alone (Karniol et al., 1975).

Even though some studies suggest that CBD may decrease some of delta^9-THC's psychoactive effects, the ratios of CBD to delta^9-THC administered in these studies are not present in marijuana used by most people. For example, in one study, researchers used smoked marijuana with ratios of CBD to delta^9-THC naturally present in marijuana plant material and they found out that varying the amount of CBD actually had no effect on delta^9-THC's psychoactive effects (Ilan et al., 2005). Because most marijuana currently available on the street has high amounts of delta^9-THC with low amounts of CBD and other cannabinoids, most individuals use marijuana with low levels of CBD present (Mehmedic et al., 2010). Thus, any possible mitigation of delta^9-THC's psychoactive effects by CBD will not occur for most marijuana users. In contrast, one study indicated that another cannabinoid present in marijuana, CBN, may enhance delta^9-THC's psychoactive effects (Karniol et al., 1975).

Behavioral Impairment

Marijuana induces various psychoactive effects that can lead to behavioral impairment. Marijuana's acute effects can significantly interfere with a person's ability to learn in the classroom or to operate motor vehicles. Acute administration of smoked marijuana impairs performance on learning, associative processes, and psychomotor behavioral tests (Block et al., 1992). Ramaekers et al. (2006a) showed that acute administration of 250 µg/kg and 500 µg/kg of delta^9-THC in smoked marijuana dose-dependently impairs cognition and motor control, including motor impulsivity and tracking impairments (Ramaekers et al., 2006b). Similarly, administration of 290 µg/kg delta^9-THC in a smoked marijuana cigarette resulted in impaired perceptual motor speed and accuracy: Two skills which are critical to driving ability (Kurzthaler et al., 1999). Lastly, administration of 3.95 percent delta^9-THC in a smoked marijuana cigarette not only increased disequilibrium measures, but also increased the latency in a task of simulated vehicle braking at a rate comparable to an increase in stopping distance of five feet at 60 mph (Liguori et al., 1998). However, acute administration of marijuana containing 2.1 percent delta^9-THC does not produce ''hangover effects'' (Chait, 1990).

In addition to measuring the acute effects immediately following marijuana administration, researchers have conducted studies to determine how long behavioral impairments last after abstinence. Some of marijuana's acute effects may not fully resolve until at least one day after the acute psychoactive effects have subsided. Heishman et al. (1990) showed that impairment on memory tasks persists for 24 hours after smoking marijuana cigarettes containing 2.57 percent delta^9-THC. However, Fant et al. (1998) showed that the morning after exposure to 1.8 percent or 3.6 percent smoked delta^9-THC, subjects had minimal residual alterations in subjective or performance measures.

A number of factors may influence marijuana's behavioral effects including the duration of use (chronic or short term), frequency of use (daily, weekly, or occasionally), and amount of use (heavy or moderate). Researchers also have examined how long behavioral impairments last following chronic marijuana use. These studies used self-reported histories of past duration, frequency, and amount of past marijuana use, and administered a variety of performance and cognitive measures at different time points following marijuana abstinence. In chronic marijuana users, behavioral impairments may persist for up to 28 days of abstinence. Solowij et al. (2002) demonstrated that after 17 hours of abstinence, 51 adult heavy chronic marijuana users performed worse on memory and attention tasks than 33 non-using controls or 51 heavy, short-term users. Another study noted that heavy, frequent marijuana users, abstinent for at least 24 hours, performed significantly worse than the controls on verbal memory and psychomotor speed tests (Messinis et al., 2006). Additionally, after at least 1 week of abstinence, young adult frequent marijuana users, aged 18–28, showed deficits in psychomotor speed, sustained attention, and cognitive inhibition (Lisdahl and Price, 2012). Adult heavy, chronic marijuana users showed deficits on memory tests after 7 days of supervised abstinence (Pope et al., 2002). However, when these same individuals were again tested after 28 days of abstinence, they did not show significant memory deficits. The authors concluded, ''cannabis-associated cognitive deficits are reversible and related to recent cannabis exposure, rather than irreversible and related to cumulative lifetime use.''[7] However, other researchers reported neuropsychological deficits in memory, executive functioning, psychomotor speed and manual dexterity in heavy marijuana users abstinent for 28 days (Bolla et al., 2002). Furthermore, a follow-up study of heavy marijuana users noted decision-making deficits after 25 days of supervised abstinence. (Bolla et al., 2005). However, moderate marijuana users did not show decision-making deficits after 25 days of abstinence, suggesting the amount of marijuana use may impact the duration of residual impairment.

The effects of chronic marijuana use do not seem to persist after more than 1 to 3 months of abstinence. After 3 months of abstinence, any deficits observed in IQ, immediate memory, delayed memory, and information-processing speeds following heavy marijuana use compared to pre-drug use scores were no longer apparent (Fried et al., 2005). Marijuana did not appear to have lasting effects on performance of a comprehensive neuropsychological battery when 54 monozygotic male twins (one of whom used marijuana, one of whom did not) were compared 1–20 years after cessation of marijuana use (Lyons et al., 2004). Similarly, following abstinence for a year or more, both light and heavy adult marijuana users did not show deficits on scores of verbal memory compared to non-using controls (Tait et al., 2011). According to a recent meta-analysis looking at non-acute and long-lasting effects of marijuana use on neurocognitive performance, any deficits seen within the first month following abstinence are generally not present after about 1 month of abstinence (Schreiner and Dunn, 2012).

Another aspect that may be a critical factor in the intensity and persistence of impairment resulting from chronic marijuana use is the age of first use. Individuals with a diagnosis of marijuana misuse or dependence who were seeking treatment for substance use, who initiated marijuana use before the age of 15 years, showed deficits in performance on tasks assessing sustained attention, impulse control, and general executive functioning compared to non-using controls. These deficits were not seen in individuals who initiated marijuana use after the age of 15 years (Fontes et al., 2011). Similarly, heavy, chronic marijuana users who began using marijuana before the age of 16 years had greater decrements in executive functioning tasks than heavy, chronic marijuana users who started using after the age of 16 years and non-using controls (Gruber et al., 2012). Additionally, in a prospective longitudinal birth cohort study of 1,037 individuals, marijuana dependence or chronic marijuana use was associated with a decrease in IQ and general neuropsychological performance compared to pre-marijuana exposure levels in adolescent onset users (Meier et al., 2012). The decline in adolescent-onset user's IQ persisted even after reduction or abstinence of marijuana use for at least 1 year. In contrast, the adult-onset chronic marijuana users showed no significant changes in IQ compared to pre-exposure levels whether they were current users or abstinent for at least 1 year (Meier et al., 2012).

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[7] In this quotation the term *Cannabis* is used interchangeably for *marijuana*.

In addition to the age of onset of use, some evidence suggests that the amount of marijuana used may relate to the intensity of impairments. In the above study by Gruber et al. (2012), where early-onset users had greater deficits than late-onset users, the early-onset users reported using marijuana twice as often and using three times as much marijuana per week than the late-onset users. Meier et al. (2012) showed that the deficits in IQ seen in adolescent-onset users increased with the amount of marijuana used. Moreover, when comparing scores for measures of IQ, immediate memory, delayed memory, and information-processing speeds to pre-drug-use levels, the current, heavy, chronic marijuana users showed deficits in all three measures while current, occasional marijuana users did not (Fried et al., 2005).

Behavioral Effects of Prenatal Exposure

Studies with children at different stages of development are used to examine the impact of prenatal marijuana exposure on performance in a series of cognitive tasks. However, many pregnant women who reported marijuana use were more likely to also report use of alcohol, tobacco, and cocaine (Goldschmidt et al., 2008). Thus, with potential exposure to multiple drugs, it is difficult to determine the specific impact of prenatal marijuana exposure.

Most studies assessing the behavioral effects of prenatal marijuana exposure included women who, in addition to using marijuana, also reported using alcohol and tobacco. However, some evidence suggests an association between heavy prenatal marijuana exposure and deficits in some cognitive domains. In both 4-year-old and 6-year-old children, heavy prenatal marijuana use is negatively associated with performance on tasks assessing memory, verbal reasoning, and quantitative reasoning (Fried and Watkinson, 1987; Goldschmidt et al., 2008). Additionally, heavy prenatal marijuana use is associated with deficits in measures of sustained attention in children at the ages of 6 years and 13–16 years (Fried et al., 1992; Fried, 2002). In 9- to 12-year-old children, prenatal marijuana exposure is negatively associated with executive functioning tasks that require impulse control, visual analysis, and hypothesis (Fried et al., 1998).

Association of Marijuana Use With Psychosis

This analysis evaluates only the evidence for a direct link between prior marijuana use and the subsequent development of psychosis. Thus, this discussion does not consider issues such as whether marijuana's transient effects are similar to psychotic symptoms in healthy individuals or exacerbate psychotic symptoms in individuals already diagnosed with schizophrenia.

Extensive research has been conducted to investigate whether exposure to marijuana is associated with the development of schizophrenia or other psychoses. Although many studies are small and inferential, other studies in the literature use hundreds to thousands of subjects. At present, the available data do not suggest a causative link between marijuana use and the development of psychosis (Minozzi et al., 2010). Numerous large, longitudinal studies show that subjects who used marijuana do not have a greater incidence of psychotic diagnoses compared to those who do not use marijuana (Fergusson et al., 2005; Kuepper et al., 2011; Van Os et al., 2002).

When analyzing the available evidence of the connection between psychosis and marijuana, it is critical to determine whether the subjects in the studies are patients who are already diagnosed with psychosis or individuals who demonstrate a limited number of symptoms associated with psychosis without qualifying for a diagnosis of the disorder. For example, instead of using a diagnosis of psychosis, some researchers relied on non-standard methods of representing symptoms of psychosis including "schizophrenic cluster" (Maremmani et al., 2004), "subclinical psychotic symptoms" (Van Gastel et al., 2012), "pre-psychotic clinical high risk" (Van der Meer et al., 2012), and symptoms related to "psychosis vulnerability" (Griffith-Lendering et al., 2012). These groupings do not conform to the criteria in the Diagnostic and Statistical Manual (DSM–5) or the International Classification of Diseases (ICD–10) for a diagnosis of psychosis. Thus, these groupings are not appropriate for use in evaluating marijuana's impact on the development of actual psychosis. Accordingly, this analysis includes only those studies that use subjects diagnosed with a psychotic disorder.

In the largest study evaluating the link between psychosis and drug use, 274 of the approximately 45,500 Swedish conscripts in the study population (<0.01 percent) received a diagnosis of schizophrenia within the 14-year period following military induction from 1969 to 1983 (Andreasson et al., 1987). Of the conscripts diagnosed with psychosis, 7.7 percent (21 of the 274 conscripts with psychosis) had used marijuana more than 50 times at induction, while 72 percent (197 of the 274 conscripts with psychosis) had never used marijuana. Although high marijuana use increased the relative risk for schizophrenia to 6.0, the authors note that substantial marijuana use history "accounts for only a minority of all cases" of psychosis (Andreasson et al., 1987). Instead, the best predictor for whether a conscript would develop psychosis was a non-psychotic psychiatric diagnosis upon induction. The authors concluded that marijuana use increased the risk for psychosis only among individuals predisposed to develop the disorder. In addition, a 35-year follow up to this study reported very similar results (Manrique-Garcia et al., 2012). In this follow up study, 354 conscripts developed schizophrenia; of these 354 conscripts, 32 used marijuana more than 50 times at induction (9 percent, an odds ratio of 6.3), while 255 had never used marijuana (72 percent).

Additionally, the conclusion that the impact of marijuana may manifest only in individuals likely to develop psychotic disorders has been shown in many other types of studies. For example, although evidence shows that marijuana use may precede the presentation of symptoms in individuals later diagnosed with psychosis (Schimmelmann et al., 2011), most reports conclude that prodromal symptoms of schizophrenia appear prior to marijuana use (Schiffman et al., 2005). Similarly, a review of the gene-environment interaction model for marijuana and psychosis concluded that some evidence supports marijuana use as a factor that may influence the development of psychosis, but only in those individuals with psychotic liability (Pelayo-Teran et al., 2012).

A similar conclusion was drawn when the prevalence of schizophrenia was modeled against marijuana use across eight birth cohorts in Australia in individuals born between the years 1940 to 1979 (Degenhardt et al., 2003). Although marijuana use increased over time in adults born during the four-decade period, there was not a corresponding increase in diagnoses for psychosis in these individuals. The authors conclude that marijuana may precipitate schizophrenic disorders only in those individuals who are vulnerable to developing psychosis. Thus, marijuana *per se* does not appear to induce schizophrenia in the majority of individuals who have tried or continue to use marijuana. However, in individuals with a genetic vulnerability for psychosis, marijuana use may influence the development of psychosis.

Cardiovascular and Autonomic Effects

Single smoked or oral doses of delta^9-THC produce tachycardia and may increase blood pressure (Capriotti et al., 1988; Benowitz and Jones, 1975). Some evidence associates the tachycardia produced by delta^9-THC with excitation of the sympathetic and depression of the parasympathetic nervous systems (Malinowska et al., 2012). During chronic marijuana ingestion, a tolerance to tachycardia develops (Malinowska et al., 2012).

However, prolonged delta^9-THC ingestion produces bradycardia and hypotension (Benowitz and Jones, 1975). Plant-derived cannabinoids and endocannabinoids elicit hypotension and bradycardia via activation of peripherally-located CB1 receptors (Wagner et al., 1998). Specifically, the mechanism of this effect is through presynaptic CB1 receptor-mediated inhibition of norepinephrine release from peripheral sympathetic nerve terminals, with possible additional direct vasodilation via activation of vascular cannabinoid receptors (Pacher et al., 2006). In humans, tolerance can develop to orthostatic hypotension (Jones, 2002; Sidney, 2002) possibly related to plasma volume expansion, but tolerance does not develop to the supine hypotensive effects (Benowitz and Jones, 1975). Additionally, electrocardiographic changes are minimal, even after large cumulative doses of delta^9-THC are administered. (Benowitz and Jones, 1975).

Marijuana smoking by individuals, particularly those with some degree of coronary artery or cerebrovascular disease, poses risks such as increased cardiac work, catecholamines and carboxyhemoglobin, myocardial infarction, and postural hypotension (Benowitz and Jones, 1981; Hollister, 1988; Mittleman et al., 2001; Malinowska et al., 2012).

Respiratory Effects

After acute exposure to marijuana, transient bronchodilation is the most typical respiratory effect (Gong et al., 1984). A recent 20-year longitudinal study with over 5,000 individuals collected information on the amount of marijuana use and pulmonary function data at years 0, 2, 5, 10, and 20 (Pletcher et al., 2012). Among the more than 5,000 individuals who participated in the study, almost 800 of them reported current marijuana use but not tobacco use at the time of assessment. Pletcher et al. (2012) found that the occasional use of marijuana is not associated with decreased pulmonary function. However, some preliminary evidence suggests that heavy marijuana use may be associated with negative pulmonary effects (Pletcher et al., 2012). Long-term use of marijuana can lead to chronic cough and increased sputum, as well as an increased frequency of chronic bronchitis and pharyngitis. In addition, pulmonary function tests reveal that large-airway obstruction can occur with chronic marijuana smoking, as can cellular inflammatory histopathological abnormalities in bronchial epithelium (Adams and Martin 1996; Hollister 1986).

Evidence regarding marijuana smoking leading to cancer is inconsistent, as some studies suggest a positive correlation while others do not (Lee and Hancox, 2011; Tashkin, 2005). Several lung cancer cases have been reported in young marijuana users with no tobacco smoking history or other significant risk factors (Fung et al., 1999). Marijuana use may dose-dependently interact with mutagenic sensitivity, cigarette smoking, and alcohol use to increase the risk of head and neck cancer (Zhang et al., 1999). However, in a large study with 1,650 subjects, a positive association was not found between marijuana and lung cancer (Tashkin et al., 2006). This finding remained true, regardless of the extent of marijuana use, when controlling for tobacco use and other potential confounding variables. Overall, new evidence suggests that the effects of marijuana smoking on respiratory function and carcinogenicity differ from those of tobacco smoking (Lee and Hancox, 2011).

Endocrine System

Experimental marijuana administration to humans does not consistently alter many endocrine parameters. In an early study, male subjects who experimentally received smoked marijuana showed a significant depression in luteinizing hormone and a significant increase in cortisol (Cone et al., 1986). However, two later studies showed no changes in hormones. Male subjects experimentally exposed to smoked delta^9-THC (18 mg/marijuana cigarette) or oral delta^9-THC (10 mg three times per day for 3 days and on the morning of the fourth day) showed no changes in plasma adrenocorticotropic hormone (ACTH), cortisol, prolactin, luteinizing hormone, or testosterone levels (Dax et al., 1989). Similarly, a study with 93 men and 56 women showed that chronic marijuana use did not significantly alter concentrations of testosterone, luteinizing hormone, follicle stimulating hormone, prolactin, or cortisol (Block et al., 1991). Additionally, chronic marijuana use did not affect serum levels of thyrotropin, thyroxine, and triiodothyronine (Bonnet, 2013). However, in a double-blind, placebo-controlled, randomized clinical trial of HIV-positive men, smoking marijuana dose-dependently increased plasma levels of ghrelin and leptin, and decreased plasma levels of peptide YY (Riggs et al., 2012).

The effects of marijuana on female reproductive system functionality differ between humans and animals. In monkeys, delta^9-THC administration suppressed ovulation (Asch et al., 1981) and reduced progesterone levels (Almirez et al., 1983). However, in women, smoked marijuana did not alter hormone levels or the menstrual cycle (Mendelson and Mello, 1984). Brown and Dobs (2002) suggest that the development of tolerance in humans may be the cause of the discrepancies between animal and human hormonal response to cannabinoids.

The presence of *in vitro* delta^9-THC reduces binding of the corticosteroid, dexamethasone, in hippocampal tissue from adrenalectomized rats, suggesting an interaction with the glucocorticoid receptor (Eldridge et al., 1991). Although acute delta^9-THC presence releases corticosterone, tolerance develops in rats with chronic administration (Eldridge et al., 1991).

Some studies support a possible association between frequent, long-term marijuana use and increased risk of testicular germ cell tumors (Trabert et al., 2011). On the other hand, recent data suggest that cannabinoid agonists may have therapeutic value in the treatment of prostate cancer, a type of carcinoma in which growth is stimulated by androgens. Research with prostate cancer cells shows that the mixed CB_1/CB_2 agonist, WIN–55212–2, induces apoptosis in prostate cancer cells, as well as decreases the expression of androgen receptors and prostate-specific antigens (Sarfaraz et al., 2005).

Immune System

Cannabinoids affect the immune system in many different ways. Synthetic, natural, and endogenous cannabinoids often cause different effects in a dose-dependent biphasic manner (Croxford and Yamamura, 2005; Tanasescu and Constantinescu, 2010).

Studies in humans and animals give conflicting results about cannabinoid effects on immune functioning in subjects with compromised immune systems. Abrams et al. (2003) investigated marijuana's effect on immunological functioning in 62 AIDS patients taking protease inhibitors. Subjects received one of the following three times a day: A smoked marijuana cigarette containing 3.95 percent delta^9-THC, an oral tablet containing delta^9-THC (2.5 mg oral dronabinol), or an oral placebo. The results showed no changes in CD4+ and CD8+ cell counts, HIV RNA levels, or protease inhibitor levels between groups. Thus, the use of cannabinoids showed no short-term adverse virologic effects in individuals with compromised immune systems. However, these human data contrast with data generated in immunodeficient mice, which demonstrated that exposure to delta^9-THC *in vivo* suppresses immune function, increases HIV co-receptor expression, and acts as a cofactor to enhance HIV replication (Roth et al., 2005).

3. The State of Current Scientific Knowledge Regarding the Drug or Other Substance

Under the third factor, the Secretary must consider the state of current scientific knowledge regarding marijuana. Thus, this section discusses the chemistry, human pharmacokinetics, and medical uses of marijuana.

Chemistry

Marijuana is one of the common names of *Cannabis sativa* L. in the family Cannabaceae.

Cannabis is one of the oldest cultivated crops, providing a source of fiber, food, oil, and drug. Botanists still debate whether *Cannabis* should be considered as a single (The Plant List, 2010) or three species, *i.e.,* C. *sativa,* C. *indica,* and C. *ruderalis* (Hillig, 2005). Specifically, marijuana is developed as sativa and indica cultivated varieties (strains) or various hybrids.

The petition defines marijuana as including all *Cannabis* cultivated strains. Different marijuana samples derived from various cultivated strains may have very different chemical constituents including delta^9 -THC and other cannabinoids (Appendino et al., 2011). As a consequence, marijuana products from different strains will have different safety, biological, pharmacological, and toxicological profiles. Thus, all *Cannabis* strains cannot be considered together because of the varying chemical constituents between strains.

Marijuana contains numerous naturally occurring constituents including cannabinoids. Overall, various *Cannabis* strains contain more than 525 identified natural constituents. Among those constituents, the most important ones are the 21 (or 22) carbon terpenoids found in the plant, as well as their carboxylic acids, analogues, and transformation products, known as cannabinoids (Agurell et al., 1984, 1986; Mechoulam, 1973; Appendino et al., 2011). Thus far, more than 100 compounds classified as cannabinoids have been characterized (ElSohly and Slade, 2005; Radwan, ElSohly et al., 2009; Appendino et al. 2011).

Cannabinoids primarily exist in *Cannabis,* and published data suggest that most major cannabinoid compounds occurring naturally have been chemically identified. New and minor cannabinoids and other new compounds are continuously being characterized (Pollastro et al., 2011). So far, only two cannabinoids (cannabigerol and its corresponding acid) have been obtained from a *non-Cannabis* source. A South African *Helichrysum (H umbraculigerum)* accumulates these compounds (Appendino et al. 2011).

Among the cannabinoids found in marijuana, delta^9-THC (alternate name delta^1-THC) and delta-8-tetrahydrocannibinol (delta^8-THC, alternate name delta^6-THC) produce marijuana's characteristic psychoactive effects. Because delta^9-THC is more abundant than delta^8-THC, marijuana's psychoactivity is largely attributed to the former. Only a few varieties of marijuana analyzed contain delta^8-THC at significant amounts (Hively et al., 1966). Delta^9-THC is an optically active resinous substance, insoluble in water, and extremely lipid soluble. Chemically, delta^9-THC is (6aR-trans)-6a,7,8,10a-tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo-[b,d]pyran-l-ol, or (−)-delta9-(trans)-tetrahydrocannabinol. The (−)-trans isomer of delta^9-THC is pharmacologically 6–100 times more potent than the (+)-trans isomer (Dewey et al., 1984).

Other cannabinoids present in marijuana include CBD, CBC, and CBN. CBD, a major cannabinoid of marijuana, is insoluble in water and lipid-soluble. Chemically, CBD is 2-[(1R,6R)-3-methyl-6-prop-1-en-2-ylcyclohex-2-en-1-yl]-5-pentylbenzene-1,3-diol. CBD does not have cannabinol-like psychoactivity (Adams and Martin, 1996; Agurell et al., 1984, 1986; Hollister, 1986). CBC is another major cannabinoid in marijuana. Chemically, CBC is 2-methyl-2-(4-methylpent-3-enyl)-7-pentyl-5-chromenol. CBN, a major metabolite of delta^9-THC, is also a minor naturally-occurring cannabinoid with weak psychoactivity. Chemically, CBN is 6,6,9-trimethyl-3-pentyl-benzo[c]chromen-1-ol.

Different marijuana samples derived from various cultivated strains may differ in chemical constituents including delta^9-THC and other cannabinoids (Appendino et al. 2011). As a consequence, marijuana products from different strains may have different safety, biological, pharmacological, and toxicological profiles. In addition to differences between cultivated strains, the concentration of delta^9-THC and other cannabinoids in marijuana may vary with growing conditions and processing after harvest. In addition to genetic differences among *Cannabis* species, the plant parts collected—for example, flowers, leaves, and stems—can influence marijuana's potency, quality, and purity (Adams and Martin, 1996; Agurell et al., 1984; Mechoulam, 1973). All these variations produce marijuana with potencies, as indicated by cannabinoid content, on average from as low as 1–2 percent to as high as 17 percent.

Overall, these variations in the concentrations of cannabinoids and other chemical constituents in marijuana complicate the interpretation of clinical data using marijuana. The lack of consistent concentrations of delta^9 -THC and other substances in marijuana from diverse sources makes interpreting the effect of different marijuana constituents difficult. In addition to different cannabinoid concentrations having different pharmacological and toxicological profiles, the non-cannabinoid components in marijuana, such as other terpenoids and flavonoids, might also contribute to the overall pharmacological and toxicological profiles of various marijuana strains and products derived from those strains.

The term marijuana is often used to refer to a mixture of the dried flowering tops and leaves from *Cannabis.* Marijuana in this limiting definition is one of three major derivatives sold as separate illicit products, which also include hashish and hash oil. According to the DEA, *Cannabis saliva* is the primary species of *Cannabis* currently marketed illegally in the United States.

Marijuana can vary in cannabinoid content and potency (Agurell et al., 1984, 1986; Mechoulam 1973, Cascini et al., 2012). In the usual mixture of leaves and stems distributed as marijuana, the concentration of delta^9-THC averages over 12 percent by weight. However, specially grown and selected marijuana can contain 15 percent or greater delta^9-THC (Appendino et al., 2011). Thus, a 1-gram marijuana cigarette might contain delta^9-THC in a range from as little as 3 milligrams to as much as 150 milligrams or more. Additionally, a recent systematic review and meta-analysis found that marijuana's delta^9-THC content has increased significantly from 1979–2009 (Cascini et al., 2012). In addition to smoking marijuana, individuals ingest marijuana through food made with butter or oil infused with marijuana and its extracts. These marijuana butters are generally made by adding marijuana to butter and heating it. The resultant butter is then used to cook a variety of foods. There are no published studies measuring the concentrations of cannabinoids in these marijuana food products.

Hashish consists of the dried and compressed cannabinoid-rich resinous material of *Cannabis* and comes in a variety of forms (*e.g.* balls and cakes). Individuals may break off pieces, place it into a pipe and smoke it. DEA reports that cannabinoid content in hashish averages six percent (DEA, 2005). With the development and cultivation of more high potency *Cannabis* strains, the average cannabinoid content in hashish will likely increase.

Hash oil is produced by solvent extraction of the cannabinoids from plant material. The extract's color and odor vary, depending on the solvent type used. Hash oil is a viscous brown- or amber-colored liquid containing approximately 50 percent cannabinoids. One or two drops of the liquid placed on a cigarette purportedly produce the equivalent of a single marijuana cigarette (DEA, 2005).

In conclusion, marijuana has hundreds of cultivars containing variable concentrations of delta^9-THC, cannabinoids, and other compounds. Thus, marijuana is not a single chemical with a consistent and reproducible chemical profile or predictable and consistent clinical effects. A guidance for industry, entitled *Botanical Drug Products,*[8] provides information on the approval of botanical drug products. To investigate marijuana for medical use in a manner acceptable as support for marketing approval under an NDA, clinical studies under an IND of consistent batches of a particular marijuana product for particular disease indications should be conducted. In addition, information and data regarding the marijuana product's chemistry, manufacturing and control, pharmacology, and animal toxicology data, among others must be provided and meet the requirements for new drug approval (See 21 CFR 314.50).

Human Pharmacokinetics

Marijuana can be taken in a variety of formulations by multiple routes of administration. Individuals smoke marijuana as a cigarette, weighing between 0.5 and 1.0 gram, or in a pipe. Additionally, individuals take marijuana orally in foods or as an extract in ethanol or other solvents. More recently, access to vaporizers provides another means for abusers to inhale marijuana,

The absorption, metabolism, and pharmacokinetic profile of delta^9-THC, cannabinoids, and drug products containing delta^9-THC vary with route of administratfon and formulation (Adams and Martin, 1996; Agurell et al., 1984, 1986).

Pharmacokinetics of Smoked Administration of Cannabinoids

Characterization of the pharmacokinetics of delta^9-THC and other cannabinoids from smoked marijuana is difficult because a subject's smoking behavior during an experiment varies (Agurell et al., 1986; Heming et al., 1986; Huestis et al., 1992a). Each puff delivers a discrete dose of delta^9-THC. An experienced marijuana smoker can titrate and regulate the dose to obtain the desired acute psychological effects and minimize undesired effects. For example, under naturalistic conditions, users hold marijuana smoke in their lungs for an extended period of time which causes prolonged absorption and increases psychoactive effects. The effect of experience in the psychological response may explain why delta^9-THC venous blood levels correlate poorly with intensity of effects and intoxication level (Agurell et al. 1986; Barnett et al. 1985; Huestis et al., 1992a). Puff and inhalation volumes should be recorded in studies as the concentration (dose) of cannabinoids administered can vary at different stages of smoking.

Smoked marijuana results in absorption of delta^9-THC in the form of an aerosol within seconds. Psychoactive effects occur immediately following absorption, with mental and behavioral effects measurable for up to 6 hours (Grotenhermen, 2003; Hollister 1986, 1988). Delta^9-THC is delivered to the brain rapidly and efficiently as expected of a very lipid soluble drug.

The bioavailability of the delta^9-THC, from marijuana in a cigarette or pipe, can range from 1 to 24 percent with the fraction absorbed rarely exceeding 10 to 20 percent (Agurell et al.,1986; Hollister, 1988). The relatively low and variable bioavailability results from significant loss of delta^9-THC in side-stream smoke, variation in individual smoking behaviors, cannabinoid pyrolysis, incomplete absorption of inhaled smoke, and metabolism in the lungs. An individual's experience and technique with smoking marijuana also determines the dose absorbed (Heming et al., 1986; Johansson et al., 1989). After smoking, delta^9-THC venous levels decline precipitously within minutes, and continue to go down to about 5 to 10 percent of the peak level within an hour (Agurell et al., 1986, Huestis et al.,1992a, 1992b).

Pharmacokinetics for Oral Administration of Cannabinoids

After oral administration of delta^9-THC or marijuana, the onset of effects starts within 30 to 90 minutes, reaches its peak after 2 to 3 hours and then remains for 4 to 12 hours (Grotenhermen, 2003; Adams and Martin, 1996; Agurell et al., 1984, 1986). Due to the delay in onset of effects, users have difficulty in titrating oral delta^9-THC doses compared to smoking marijuana. Oral bioavailability of delta^9-THC, whether pure or in marijuana, is low and extremely variable, ranging between 5 and 20 percent (Agurell et al., 1984, 1986). Following oral administration of radioactive-labeled delta^9-THC, delta^9-THC plasma levels are low relative to plasma levels after smoking or intravenous administration. Inter- and intra-subject variability occurs even with repeated dosing under controlled conditions. The low and variable oral bioavailability of delta^9-THC is a consequence of its first-pass hepatic elimination from blood and erratic absorption from stomach and bowel.

Cannabinoid Metabolism and Excretion

Cannabinoid metabolism is complex. Delta^9-THC is metabolized via microsomal hydroxylation to both active and inactive metabolites (Lemberger et al., 1970, 1972a, 1972b; Agurell et al., 1986; Hollister, 1988). The primary active metabolite of delta^9-THC following oral ingestion is 11-hydroxy-delta^9-THC. This metabolite is approximately equipotent to delta^9-THC in producing marijuana-like subjective effects (Agurell et al., 1986, Lemberger and Rubin, 1975). After oral administration, metabolite levels may exceed that of delta^9-THC and thus contribute greatly to the pharmacological effects of oral delta^9-THC or marijuana.

Plasma clearance of delta^9-THC approximates hepatic blood flow at about 950 ml/min or greater. The rapid disappearance of delta^9-THC from blood is largely due to redistribution to other tissues in the body, rather than to metabolism (Agurell et al., 1984, 1986). Metabolism in most tissues is relatively slow or absent. Slow release of $delta^9$-THC and other cannabinoids from tissues and subsequent metabolism results in a long elimination half-life. The terminal half-life of $delta^9$-THC ranges from approximately 20 hours to as long as 10 to 13 days, though reported estimates vary as expected with any slowly cleared substance and the use of assays with variable sensitivities (Hunt and Jones, 1980). Lemberger et al. (1970) determined the half-life of $delta^9$-THC to range from 23 to 28 hours in heavy marijuana users to 60 to 70 hours in naive users. In addition to 11-hydroxy-$delta^9$-THC, some inactive carboxy metabolites have terminal half-lives of 50 hours to 6 days or more. The latter substances serve as long-term markers in urine tests for earlier marijuana use.

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[8] This guidance is available on the Internet at *http://www.fda.gov/Drugs/default.htm* under Guidance (Drugs).

The majority of the absorbed $delta^9$-THC dose is eliminated in feces, and about 33 percent in urine. $Delta^9$-THC enters enterohepatic circulation and undergoes hydroxylation and oxidation to 11-nor-9-carboxy-$delta^9$-THC. The glucuronide is excreted as the major urine metabolite along with about 18 non-conjugated metabolites. Frequent and infrequent marijuana users metabolize $delta^9$-THC similarly (Agurell et al., 1986).

Status of Research Into the Medical Uses for Marijuana

State-level public initiatives, including laws and referenda in support of the medical use of marijuana, have generated interest in the medical community and the need for high quality clinical investigation as well as comprehensive safety and effectiveness data. In order to address the need for high quality clinical investigations, the state of California established the Center for Medicinal Cannabis Research (CMCR, *www.cmcr.ucsd.edu*) in 2000 "in response to scientific evidence for therapeutic possibilities of cannabis[9] and local legislative initiatives in favor of compassionate use" (Grant, 2005). State legislation establishing the CMCR called for high quality medical research that would "enhance understanding of the efficacy and adverse effects of marijuana as a pharmacological agent," but stressed the project "should not be construed as encouraging or sanctioning the social or recreational use of marijuana." The CMCR funded many of the published studies on marijuana's potential use for treating multiple sclerosis, neuropathic pain, appetite suppression and cachexia. However, aside from the data produced by CMCR, no state-level medical marijuana laws have produced scientific data on marijuana's safety and effectiveness.

FDA approves medical use of a drug following a submission and review of an NDA or BLA. The FDA has not approved any drug product containing marijuana for marketing. Even so, results of small clinical exploratory studies have been published in the current medical literature. Many studies describe human research with marijuana in the United States under FDA-regulated IND applications.

However, FDA approval of an NDA is not the only means through which a drug can have a currently accepted medical use in treatment in the United States. In general, a drug may have a "currently accepted medical use" in treatment in the United States if the drug meets a five-part test. Established case law (Alliance for Cannabis Therapeutics v. DEA, 15 F.3d 1131, 1135 (D.C. Cir. 1994)) upheld the Administrator of DEA's application of the five-part test to determine whether a drug has a "currently accepted medical use." The following describes the five elements that characterize "currently accepted medical use" for a drug:[10]

i. the drug's chemistry must be known and reproducible.

"The substance's chemistry must be scientifically established to permit it to be reproduced into dosages which can be standardized. The listing of the substance in a current edition of one of the official compendia, as defined by section 201 G) of the Food, Drug and Cosmetic Act, 21 U.S.C. 321G), is sufficient to meet this requirement."

ii. there must be adequate safety studies.

"There must be adequate pharmacological and toxicological studies, done by all methods reasonably applicable, on the basis of which it could fairly and responsibly be concluded, by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, that the substance is safe for treating a specific, recognized disorder."

iii. there must be adequate and well-controlled studies proving efficacy.

"There must be adequate, well-controlled, well-designed, well-conducted, and well-documented studies, including clinical investigations, by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, on the basis of which it could be fairly and responsibly concluded by such experts that the substance will have the intended effect in treating a specific, recognized disorder."

iv. the drug must be accepted by qualified experts.

"The drug has a New Drug Application (NDA) approved by the Food and Drug Administration, pursuant to the Food, Drug and Cosmetic Act, 21 U.S.C. 355. Or, a consensus of the national community of experts, qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, accepts the safety and effectiveness of the substance for use in treating a specific, recognized disorder. A material conflict of opinion among experts precludes a finding of consensus." and

v. the scientific evidence must be widely available.

"In the absence of NDA approval, information concerning the chemistry, pharmacology, toxicology, and effectiveness of the substance must be reported, published, or otherwise widely available, in sufficient detail to permit experts, qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, to fairly and responsibly conclude the substance is safe and effective for use in treating a specific, recognized disorder."

Marijuana does not meet any of the five elements necessary for a drug to have a "currently accepted medical use."

Firstly, the chemistry of marijuana, as defined in the petition, is not reproducible in terms of creating a standardized dose. The petition defines marijuana as including all *Cannabis* cultivated strains. Different marijuana samples derived from various cultivated strains may have very different chemical constituents including $delta^9$-THC and other cannabinoids (Appendino et al., 2011). As a consequence, marijuana products from different strains will have different safety, biological, pharmacological, and toxicological profiles. Thus, when considering all *Cannabis* strains together, because of the varying chemical constituents, reproducing consistent standardized doses is not possible. Additionally, smoking marijuana currently has not been shown to allow delivery of consistent and reproducible doses. However, if a specific *Cannabis* strain is grown and processed under strictly controlled conditions, the plant chemistry may be kept consistent enough to produce reproducible and standardized doses.

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[9] In this quotation the term cannabis is interchangeable with marijuana.

[10] 57 FR 10499, 10504–06 (March 26, 1992).

As to the second and third criteria; there are neither adequate safety studies nor adequate and well-controlled studies proving marijuana's efficacy. To support the petitioners' assertion that marijuana has accepted medical use, the petitioners cite the American Medical Association's (AMA) 2009 report entitled "Use of Cannabis for Medicinal Purposes." The petitioners claim the AMA report is evidence the AMA accepts marijuana's safety and efficacy. However, the 2009 AMA report clarifies that the report "should not be viewed as an endorsement of state-based medical cannabis programs, the legalization of marijuana, or that scientific evidence on the therapeutic use of cannabis meets the same and current standards for a prescription drug product."[11]

Currently, no published studies conducted with marijuana meet the criteria of an adequate and well-controlled efficacy study. The criteria for an adequate and well-controlled study for purposes of determining the safety and efficacy of a human drug are defined under the Code of Federal Regulations (CFR) in 21 CFR 314.126. In order to assess this element, FDA conducted a review of clinical studies published and available in the public domain before February, 2013. Studies were identified through a search of PubMed[12] for articles published from inception to February 2013, for randomized controlled trials using marijuana to assess marijuana's efficacy in any therapeutic indication. Additionally, the review included studies identified through a search of bibliographic references in relevant systematic reviews and identified studies presenting original research in any language. Selected studies needed to be placebo-controlled and double-blinded. Additionally, studies needed to encompass administered marijuana plant material. There was no requirement for any specific route of administration, nor any age limits on study subjects. Studies were excluded that used placebo marijuana supplemented by the addition of specific amounts of THC or other cannabinoids. Additionally, studies administering marijuana plant extracts were excluded.

The PubMed search yielded a total of 566 abstracts of scientific articles. Of these abstracts, a full-text review was conducted with 85 papers to assess eligibility. Of the studies identified through the search of the references and the 566 abstracts from the PubMed search, only 11 studies met all the criteria for selection (Abrams et al., 2007; Corey-Bloom et al., 2012; Crawford and Merritt, 1979; Ellis et al., 2009; Haney et al., 2005; Haney et al., 2007; Merritt et al., 1980; Tashkin et al., 1974; Ware et al., 2010; Wilsey et al., 2008; Wilsey et al., 2013). These 11 studies were published between 1974 and 2013. Ten of these studies were conducted in the United States and one study was conducted in Canada. The identified studies examine the effects of smoked and vaporized marijuana for the indications of chronic neuropathic pain, spasticity related to Multiple Sclerosis (MS), appetite stimulation in human immunodeficiency virus (HIV) patients, glaucoma, and asthma. All studies used adult subjects.

The 11 identified studies were individually evaluated to determine if they successfully meet accepted scientific standards. Specifically, they were evaluated on study design including subject selection criteria, sample size, blinding techniques, dosing paradigms, outcome measures, and the statistical analysis of the results. The analysis relied on published studies, thus information available about protocols, procedures, and results were limited to documents published and widely available in the public domain. The review found that all 11 studies that examined effects of inhaled marijuana do not currently prove efficacy of marijuana in any therapeutic indication based on a number of limitations in their study design; however, they may be considered proof of concept studies. Proof of concept studies provide preliminary evidence on a proposed hypothesis involving a drug's effect. For drugs under development, the effect often relates to a short-term clinical outcome being investigated. Proof of concept studies often serve as the link between preclinical studies and dose ranging clinical studies. Thus, proof of concept studies generally are not sufficient to prove efficacy of a drug because they provide only preliminary information about the effects of a drug.

In addition to the lack of published adequate and well-controlled efficacy studies proving efficacy, the criteria for adequate safety studies has also not been met. Importantly, in its discussion of the five-part test used to determine whether a drug has a "currently accepted medical use," DEA said, "No drug can be considered safe in the abstract. Safety has meaning only when judged against the intended use of the drug, its known effectiveness, its known and potential risks, the severity of the illness to be treated, and the availability of alternative remedies" (57 FR 10504). When determining whether a drug product is safe and effective for any indication, FDA performs an extensive risk-benefit analysis to determine whether the risks posed by the drug product's side effects are outweighed by the drug product's potential benefits for a particular indication. Thus, contrary to the petitioner's assertion that marijuana has accepted safety, in the absence of an accepted therapeutic indication which can be weighed against marijuana's risks, marijuana does not satisfy the element for having adequate safety studies such that experts may conclude that it is safe for treating a specific, recognized disorder.

The fourth of the five elements for determining "currently accepted medical use" requires that the national community of experts, qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, accepts the safety and effectiveness of the substance for use in treating a specific, recognized disorder. A material conflict of opinion among experts precludes a finding of consensus. Medical practitioners who are not experts in evaluating drugs are not qualified to determine whether a drug is generally recognized as safe and effective or meets NDA requirements (57 FR 10499–10505).

There is no evidence that there is a consensus among qualified experts that marijuana is safe and effective for use in treating a specific, recognized disorder. As discussed above, there are not adequate scientific studies that show marijuana is safe and effective in treating a specific, recognized disorder. In addition, there is no evidence that a consensus of qualified experts have accepted the safety and effectiveness of marijuana for use in treating a specific, recognized disorder. Although medical practitioners are not qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, we also note that the AMA's report, entitled "Use of Cannabis for Medicinal Purposes," does not accept that marijuana currently has accepted medical use. Furthermore, based on the above definition of a "qualified expert", who is an individual qualified by scientific training and experience to evaluate the safety and effectiveness of a drug, state-level medical marijuana laws do not provide evidence of a consensus among qualified experts that marijuana is safe and effective for use in treating a specific, recognized disorder.

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[11] In this quotation the term cannabis is used interchangeably for marijuana.

[12] The following search strategy was used, "(cannabis OR marijuana) AND (therapeutic use OR therapy) AND (RCT OR randomized controlled trial OR "systematic review" OR clinical trial OR clinical trials) NOT ("marijuana abuse"[Mesh] OR addictive behavior OR substance related disorders)."

As to the fifth part of the test, which requires that information concerning the chemistry, pharmacology, toxicology, and effectiveness of marijuana to be reported in sufficient detail, the scientific evidence regarding all of these aspects is not available in sufficient detail to allow adequate scientific scrutiny. Specifically, the scientific evidence regarding marijuana's chemistry in terms of a specific *Cannabis* strain that could produce standardized and reproducible doses is not currently available.

Alternately, a drug can be considered to have a "currently accepted medical use with severe restrictions" (21 U.S.C. 812(b)(2)(B)), as allowed under the stipulations for a Schedule II drug. Yet, as stated above, currently marijuana does not have any accepted medical use, even under conditions where its use is severely restricted.

In conclusion, to date, research on marijuana's medical use has not progressed to the point where marijuana is considered to have a "currently accepted medical use" or a "currently accepted medical use with severe restrictions."

4. Its History and Current Pattern of Abuse

Under the fourth factor, the Secretary must consider the history and current pattern of marijuana abuse. A variety of sources provide data necessary to assess abuse patterns and trends of marijuana. The data indicators of marijuana use include the NSDUH, MTF, DAWN, and TEDS. The following briefly describes each data source, and summarizes the data from each source.

National Survey on Drug Use and Health (NSDUH)[13]

According to 2012 NSDUH[14] data, the most recent year with complete data, the use of illicit drugs, including marijuana, is increasing. The 2012 NSDUH estimates that 23.9 million individuals over 12 years of age (9.2 percent of the U.S. population) currently use illicit drugs, which is an increase of 4.8 million individuals from 2004 when 19.1 million individuals (7.9 percent of the U.S. population) were current illicit drug users. NSDUH reports marijuana as the most commonly used illicit drug, with 18.9 million individuals (7.3 percent of the U.S. population) currently using marijuana in 2012. This represents an increase of 4.3 million individuals from 2004, when 14.6 million individuals (6.1 percent of the U.S. population) were current marijuana users.

The majority of individuals who try marijuana at least once in their lifetime do not currently use marijuana. The 2012 NSDUH estimates that 111.2 million individuals (42.8 percent of the U.S. population) have used marijuana at least once in their lifetime. Based on this estimate and the estimate for the number of individuals currently using marijuana, approximately 16.9 percent of those who have tried marijuana at least once in their lifetime currently use marijuana; conversely, 83.1 percent do not currently use marijuana. In terms of the frequency of marijuana use, an estimated 40.3 percent of individuals who used marijuana in the past month used marijuana on 20 or more days within the past month. This amount corresponds to an estimated 7.6 million individuals who used marijuana on a daily or almost daily basis.

Some characteristics of marijuana users are related to age, gender, and criminal justice system involvement. In observing use among different age cohorts, the majority of individuals who currently use marijuana are shown to be between the ages of 18–25, with 18.7 percent of this age group currently using marijuana. In the 26 and older age group, 5.3 percent of individuals currently use marijuana. Additionally, in individuals aged 12 years and older, males reported more current marijuana use than females.

NSDUH includes a series of questions aimed at assessing the prevalence of dependence and abuse of different substances in the past 12 months.[15] In 2012, marijuana was the most common illicit drug reported by individuals with past year dependence or abuse. An estimated 4.3 million individuals meet the NSDUH criteria for marijuana dependence or abuse in 2012. The estimated rates and number of individuals with marijuana dependence or abuse has remained similar from 2002 to 2012. In addition to data on dependence and abuse, NSDUH includes questions aimed at assessing treatment for a substance use problem.[16] In 2012, an estimated 957,000 persons received treatment for marijuana use during their most recent treatment in the year prior to the survey.

Monitoring the Future (MTF)[17]

According to MTF,[18] rates of marijuana and illicit drug use declined for all three grades from 2005 through 2007. However, starting around 2008, rates of annual use of illicit drugs and marijuana increased through 2013 for all three grades. Marijuana remained the most widely used illicit drug during all time periods. The prevalence of annual and past month marijuana use in 10th and 12th graders in 2013 is greater than in 2005. Table 1 lists the lifetime, annual, and monthly prevalence rates of various drugs for 8th, 10th, and 12th graders in 2013.

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[13] NSDUH provides national estimates of the prevalence and incidence of illicit drug, alcohol and tobacco use in the United States. NSDUH is an annual study conducted by SAMHSA. Prior to 2002, the database was known as the National Household Survey on Drug Abuse (NHSDA). NSDUH utilizes a nationally representative sample of United States civilian, non-institutionalized population aged 12 years and older. The survey excludes homeless people who do not use shelters, active military personnel, and residents of institutional group quarters such as jails and hospitals. The survey identifies whether an individual used a drug within a specific time period, but does not identify the amount of the drug used on each occasion. NSDUH defines "current use" as having used the substance within the month prior to the study.

[14] 2013; *http://www.samhsa.gov/data/NSDUH.aspx.*

[15] "These questions are used to classify persons as dependent on or abusing specific substances based on criteria specified in the *Diagnostic and Statistical Manual of Mental Disorder,* 4th edition (DSM–IV). The questions related to dependence ask about health and emotional problems associated with substance use, unsuccessful attempts to cut down on use, tolerance, withdrawal, reducing other activities to use substances, spending a lot time engaging in activities related to substance use, or using the substance in greater quantities or for longer time than intended. The questions on abuse ask about problems at work, home, and school; problems with family or friends; physical danger; and trouble with the law due to substance use. Dependence is considered to be a more severe substance use problem than abuse because it involves the psychological and physiological effects of tolerance and withdrawal." (NSDUH, 2013).

[16] "Estimates . . . refer to treatment received for illicit drug or alcohol use, or for medical problems associated with the use of illicit drugs or alcohol. This includes treatment received in the past year at any location, such as a hospital (inpatient), rehabilitation facility (outpatient or inpatient), mental health center, emergency room, private doctor's office, prison or jail, or a self-help group, such as Alcoholics Anonymous or Narcotics Anonymous." (NSDUH, 2013).

[17] Monitoring the Future is a national survey that tracks drug use prevalence and trends among adolescents in the United States. MTF is reported annually by the Institute for Social Research at the University of Michigan under a grant from NIDA. Every spring, MTF surveys 8th, 10th, and 12th graders in randomly selected U.S. schools. MTF has been conducted since 1975 for 12th graders and since 1991 for 8th and 10th graders. The MTF survey presents data in terms of prevalence among the sample interviewed. For 2012, the latest year with complete data, the sample sizes were 15,200—8th graders; 13,300—10th graders; and 13,200—12th graders. In all, a total of about 41,700 students of 389 schools participated in the 2013 MTF.

[18] 2013; *http://www.monitoringthefuture.org/index.html.*

Table 1: Trends in lifetime, annual, and monthly prevalence of use of various drugs for eighth, tenth, and twelfth graders. Percentages represent students in survey responding that they had used a drug at least once in their lifetime, in the past year, or in the past 30 days.

	Lifetime			Annual			30-Day		
	2011	2012	2013	2011	2012	2013	2011	2012	2013
Any illicit Drug (a)									
8th Grade	20.1	18.5	20.3	14.7	13.4	14.9	8.5	7.7	8.5
10th Grade	37.7	36.8	38.8	31.1	30.1	31.8	19.2	18.6	19.4
12th Grade	49.9	49.1	50.4	40.0	39.7	40.3	25.2	25.2	25.5
Marijuana/Hashish									
8th Grade	16.4	15.2	16.5	12.5	11.4	12.7	7.2	6.5	7.0
10th Grade	34.5	33.8	35.8	28.8	28.0	29.8	17.6	17.0	18.0
12th Grade	45.5	45.2	45.5	36.4	36.4	36.4	22.6	22.9	22.7

SOURCE: The Monitoring the Future Study, the University of Michigan
a. For 12th graders only: "any illicit drug" includes any use of marijuana, LSD, other hallucinogens, crack, other cocaine, or heroin; or any narcotics use other than heroin, amphetamines, sedatives (barbiturates), or tranquilizers not under a doctor's orders. For 8th and 10th graders only: the use of narcotics other than heroin and sedatives (barbiturates) was excluded.

Drug Abuse Warning Network (DAWN)[19]

Importantly, many factors can influence the estimates of ED visits, including trends in overall use of a substance as well as trends in the reasons for ED usage. For instance, some drug users may visit EDs for life-threatening issues while others may visit to seek care for detoxification because they needed certification before entering treatment. Additionally, DAWN data do not distinguish the drug responsible for the ED visit from other drugs that may have been used concomitantly. As stated in a DAWN report, "Since marijuana/hashish is frequently present in combination with other drugs, the reason for the ED visit may be more relevant to the other drug(s) involved in the episode."

For 2011, DAWN[20] estimates a total of 5,067,374 (95 percent confidence interval [CI]: 4,616,753 to 5,517,995) drug-related ED visits from the entire United States. Of these, approximately 2,462,948 ([CI]: 2,112,868 to 2,813,028) visits involved drug misuse or abuse.

During the same period, DAWN estimates that 1,252,500 (CI: 976,169 to 1,528,831) drug related ED visits involved illicit drugs. Thus, over half of all drug-related ED visits associated with drug misuse or abuse involved an illicit drug. For ED visits involving illicit drugs, 56.3 percent involved multiple drugs while 43.7 percent involved a single drug.

Marijuana was involved in 455,668 ED visits (CI: 370,995 to 540,340), while cocaine was involved in 505,224 (CI: 324,262 to 686, 185) ED visits, heroin was involved in 258,482 (CI: 205,046 to 311,918) ED visits and stimulants including amphetamine and methamphetamine were involved in 159,840 (CI: 100,199 to 219,481) ED visits. Other illicit drugs, such as PCP, MDMA, GHB and LSD were much less frequently associated with ED visits. The number of ED visits involving marijuana has increased by 62 percent since 2004.

Marijuana-related ED visits were most frequent among young adults and minors. Individuals under the age of 18 accounted for 13.2 percent of these marijuana-related visits, whereas this age group accounted for approximately 1.2 percent of ED visits involving cocaine, and less than 1 percent of ED visits involving heroin. However, the age group with the most marijuana-related ED visits was between 25 and 29 years old. Yet, because populations differ between age groups, a standardized measure for population size is useful to make comparisons. For marijuana, the rates of ED visits per 100,000 population were highest for patients aged 18 to 20 (443.8 ED visits per 100,000) and for patients aged 21 to 24 (446.9 ED visits per 100,000).

While DAWN provides estimates for ED visits associated with the use of medical marijuana for 2009–2011, the validity of these estimates is questionable. Because the drug is not approved by the FDA, reporting medical marijuana may be inconsistent and reliant on a number of factors including whether the patient self-reports the marijuana use as medicinal, how the treating health care provider records the marijuana use, and lastly how the SAMHSA coder interprets the report. All of these aspects will vary greatly between states with medical marijuana laws and states without medical marijuana laws. Thus, even though estimates are reported for medical marijuana related ED visits, medical marijuana estimates cannot be assessed with any acceptable accuracy at this time, as FDA has not approved marijuana treatment of any medical condition. These data show the difficulty in evaluating abuse of a product that is not currently approved by FDA, but authorized for medical use, albeit inconsistently, at the state level. Thus, we believe the likelihood of the treating health care provider or SAMHSA coder attributing the ED visit to "medical marijuana" versus "marijuana" to be very low. Overall, the available data are inadequate to characterize its abuse at the community level.

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[19] DAWN is a national probability survey of the U.S. hospitals with ED designed to obtain information on drug related ED visits. DAWN is sponsored by SAMHSA. The DAWN system provides information on the health consequences of drug use in the United States, as manifested by drug-related visits to ED. The ED data from a representative sample of hospital emergency departments are weighted to produce national estimates. Importantly, DAWN data and estimates, starting in 2004, are not comparable to those for prior years because of vast changes in the methodology used to collect the data. Furthermore, estimates for 2004 are the first to be based on a redesigned sample of hospitals, which ended in 2011.

[20] 2011; *http://www.samhsa.gov/data/dawn.aspx.*

Treatment Episode Data Set (TEDS)[21]

Primary marijuana abuse accounted for 18.1 percent of all 2011 TEDS[22] admissions. Individuals admitted for primary marijuana abuse were nearly three-quarters (73.4 percent) male, and almost half (45.2 percent) were white. The average age at admission was 24 years old, and 31.1 percent of individuals admitted for primary marijuana abuse were under the age of 18. The reported frequency of marijuana use was 24.3 percent reporting daily use. Almost all (96.8 percent) primary marijuana users utilized the substance by smoking. Additionally, 92.9 percent reported using marijuana for the first time before the age of 18.

An important aspect of TEDS admission data for marijuana is of the referral source for treatment. Specifically, primary marijuana admissions were less likely than all other admissions to either be self-referred or referred by an individual for treatment. Instead, the criminal justice system referred more than half (51.6 percent) of primary marijuana admissions.

Since 2003, the percent of admissions for primary marijuana abuse increased from 15.5 percent of all admissions in 2003 to 18.1 percent in 2011. This increase is less than the increase seen for admissions for primary opioids other than heroin, which increased from 2.8 percent in 2003 to 7.3 percent in 2011. In contrast, the admissions for primary cocaine abuse declined from 9.8 percent in 2003 to 2.0 percent in 2011.

5. The Scope, Duration, and Significance of Abuse

Under the fifth factor, the Secretary must consider the scope, duration, and significance of marijuana abuse. According to 2012 data from NSDUH and 2013 data from MTF, marijuana remains the most extensively used illegal drug in the United States, with 42.8 percent of U.S. individuals over age 12 (111.2 million) and 45.5 percent of 12th graders having used marijuana at least once in their lifetime. Although the majority of individuals over age 12 (83.1 percent) who have ever used marijuana in their lifetime do not use the drug monthly, 18.9 million individuals (7.3 percent of the U.S. population) report that they used marijuana within the past 30 days. An examination of use among various age cohorts through NSDUH demonstrates that monthly use occurs primarily among college-aged individuals, with use dropping off sharply after age 25. Additionally, NSDUH data show the number of individuals reporting past-month use of marijuana has increased by 4.3 million individuals since 2004. Data from MTF shows that annual prevalence of marijuana use declined for all three grades from 2005 through 2007, then began to rise through 2013. Additionally, in 2013, 1.1 percent of 8th graders, 4.0 percent of 10th graders, and 6.5 percent of 12th graders reported daily use of marijuana, defined as use on 20 or more days within the past 30 days.

The 2011 DAWN data show that marijuana use was mentioned in 455,668 ED visits, which amounts to approximately 36.4 percent of all illicit drug-related ED visits.[23]

TEDS data for 2011 show that 18.1 percent of all admissions were for primary marijuana abuse.[24] Between 2003 and 2011, there was a 2.6 percent increase in the number of TEDS admissions for primary marijuana use. Approximately 61.5 percent of primary marijuana admissions in 2011 were for individuals under the age of 25 years.

6. WHAT, if Any, Risk There Is to the Public Health

Under the sixth factor, the Secretary must consider the risks posed to the public health by marijuana. Factors 1, 4, and 5 include a. discussion of the risk to the public health as measured by emergency room episodes and drug treatment admissions. Additionally, Factor 2 includes a discussion of marijuana's central nervous system, cognitive, cardiovascular, autonomic, respiratory, and immune system effects. Factor 6 focuses on the health risks to the individual user in terms of the risks from acute and chronic use of marijuana, as well as the "gateway hypothesis."

Risks From Acute Use of Marijuana

Acute use of marijuana impairs psychomotor performance, including complex task performance, which makes operating motor vehicles or heavy equipment after using marijuana inadvisable (Ramaekers et al., 2004; Ramaekers et al., 2006a). A meta-analysis conducted by Li et al. (2011) showed an association between marijuana use by the driver and a significantly increased risk of involvement in a car accident. Additionally, in a minority of individuals who use marijuana, some potential responses include dysphoria and psychological distress, including prolonged anxiety reactions (Haney et al., 1999).

Risks From Chronic Use of Marijuana

A distinctive marijuana withdrawal syndrome following long term or chronic use has been identified. The withdrawal syndrome indicates that marijuana produces physical dependence that is mild, short-lived, and comparable to tobacco withdrawal (Budney et al., 2008). Marijuana withdrawal syndrome is described in detail below under Factor 7.

The following states how the DSM–V (2013) of the American Psychiatric Association describes the consequences of *Cannabis*[25] abuse:

> Individuals with cannabis use disorder may use cannabis throughout the day over a period of months or years, and thus may spend many hours a day under the influence. Others may use less frequently, but their use causes recurrent problems related to family,

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[21] The TEDS system is part of SAMHSA's Drug and Alcohol Services Information System (Office of Applied Science, SAMHSA). The TEDS report presents information on the demographic and substance use characteristics of the 1.8 million annual admissions to treatment for alcohol and drug abuse in facilities that report to individual state administrative data systems. Specifically, TEDS includes facilities licensed or certified by the states to provide substance abuse treatment and is required by the states to provide TEDS client-level data. Facilities that report TEDS data are those receiving State alcohol and drug agency funds for the provision of alcohol and drug treatment services. Since TEDS is based only on reports from these facilities, TEDS data do not represent the total national demand for substance abuse treatment or the prevalence of substance abuse in the general population. The primary goal for TEDS is to monitor the characteristics of treatment .episodes for substance abusers. Importantly, TEDS is an admissions-based system, where admittance to treatment is counted as an anonymous tally. For instance, a given individual who is admitted to treatment twice within a given year would be counted as two admissions. The most recent year with complete data is 2011.

[22] 2011; *http://www.samhsa.gov/data/DASIS.aspx?qr=t#TEDS.*

[23] Many factors can influence the estimates of ED visits, including trends in the reasons for ED usage. For instance, some drug users may visit EDs for life-threatening issues while others may visit to seek care for detoxification because they needed certification before entering treatment. Additionally, DAWN data do not distinguish the drug responsible for the ED visit from other drugs that may have been used concomitantly. As stated in a DAWN report, "Since marijuana/hashish is frequently present in combination with other drugs, the reason for the ED visit may be more relevant to the other drug(s) involved in the episode."

[24] An important aspect of TEDS admission data for marijuana is of the referral source for treatment. Specifically, primary marijuana admissions were less likely than all other admissions to either be self-referred or referred by an individual for treatment. Instead, the criminal justice system referred more than half (51.6 percent) of primary marijuana admissions.

[25] *Cannabis* is the term used in the DSM–V to refer to marijuana. In the following excerpt the term *Cannabis* is interchangeable for the term *marijuana.*

school, work, or other important activities (*e.g.,* repeated absences at work; neglect of family obligations). Periodic cannabis use and intoxication can negatively affect behavioral and cognitive functioning and thus interfere with optimal performance at work or school, or place the individual at increased physical risk when performing activities that could be physically hazardous (*e.g.,* driving a car; playing certain sports; performing manual work activities, including operating machinery). Arguments with spouses or parents over the use of cannabis in the home, or its use in the presence of children, can adversely impact family functioning and are common features of those with cannabis use disorder. Last, individuals with cannabis use disorder may continue using marijuana despite knowledge of physical problems (*e.g.,* chronic cough related to smoking) or psychological problems (*e.g.,* excessive sedation or exacerbation of other mental health problems) associated with its use.

Marijuana as a "Gateway Drug"

Kandel (1975) proposed nearly 40 years ago the hypothesis that marijuana is a "gateway drug" that leads to the use or abuse of other illicit drugs. Since that time, epidemiological research explored this premise. Overall, research does not support a direct causal relationship between regular marijuana use and other illicit drug use. The studies examining the gateway hypothesis are limited. First, in general, studies recruit individuals influenced by a myriad of social, biological, and economic factors that contribute to extensive drug abuse (Hall & Lynskey, 2005). Second, most studies that test the hypothesis that marijuana use causes abuse of illicit drugs use the determinative measure *any use of an illicit drug,* rather than DSM–5 criteria for drug abuse or dependence on an illicit drug (DSM–5, 2013). Consequently, although an individual who used marijuana may try other illicit drugs, the individual may not regularly use drugs, or have a diagnosis of drug abuse or dependence.

Little evidence supports the hypothesis that initiation of marijuana use leads to an abuse disorder with other illicit substances. For example, one longitudinal study of 708 adolescents demonstrated that early onset marijuana use did not lead to problematic drug use (Kandel & Chen, 2000). Similarly, Nace et al. (1975) examined Vietnam-era soldiers who extensively abused marijuana and heroin while they were in the military, and found a lack of correlation of a causal relationship demonstrating marijuana use leading to heroin addiction. Additionally, in another longitudinal study of 2,446 adolescents, marijuana dependence was uncommon but when it did occur, the common predictors of marijuana dependence were the following: Parental death, deprived socio-economic status, and baseline illicit drug use other than marijuana (von Sydow et al., 2002).

When examining the association between marijuana and illicit drugs, focusing on drug use versus abuse or dependence, different patterns emerge. For example, a study examining the possible causal relationship of the gateway hypothesis found a correlation between marijuana use in adolescents and other illicit drug use in early adulthood and, adjusting for age-linked experiences, did not effect this correlation (Van Gundy and Rebellon, 2010). However, when examining the association in terms of development of drug abuse; age-linked stressors and social roles moderated the correlation between marijuana use in adolescents and other illicit drug abuse. Similarly, Degenhardt et al. (2009) examined the development of drug dependence and found an association that did not support the gateway hypothesis. Specifically, drug dependence was significantly associated with the use of other illicit drugs prior to marijuana use.

Interestingly, the order of initiation of drug use seems to depend on the prevalence of use of each drug, which varies by country. Based on the World Health Organization (WHO) World Mental Health Survey that includes data from 17 different countries, the order of drug use initiation varies by country and relates to prevalence of drug use in each country (Degenhardt et al., 2010). Specifically, in the countries with the lowest prevalence of marijuana use, use of other illicit drugs before marijuana was common. This sequence of initiation is less common in countries with higher prevalence of marijuana use. A study of 9,282 households in the United States found that marijuana use often preceded the use of other illicit drugs; however, prior non-marijuana drug dependence was also frequently correlated with higher levels of illicit drug abuse (Degenhardt et al., 2009). Additionally, in a large 25-year longitudinal study of 1,256 New Zealand children, the author concluded that marijuana use correlated to an increased risk of abuse of other drugs, including cocaine and heroin (Fergusson et al., 2005).

Although many individuals with a drug abuse disorder may have used marijuana as one of their first illicit drugs, this fact does not correctly lead to the reverse inference that most individuals who used marijuana will inherently go on to try or become regular users of other illicit drugs. Specifically, data from the 2011 NSDUH survey illustrates this issue (SAMHSA, 2012). NSDUH data estimates 107.8 million individuals have a lifetime history of marijuana use, which indicates use on at least one occasion, compared to approximately 36 million individuals having a lifetime history of cocaine use and approximately 4 million individuals having a lifetime history of heroin use. NSDUH data do not provide information about each individual's specific drug history. However, even if one posits that every cocaine and heroin user previously used marijuana, the NSDUH data show that marijuana use at least once in a lifetime does not predict that an individual will also use another illicit drug at least once.

Finally, a review of the gateway hypothesis by Vanyukov et al. (2012) notes that because the gateway hypothesis only addresses the order of drug use initiation, the gateway hypothesis does not specify any mechanistic connections between drug "stages" following exposure to marijuana and does not extend to the risks for addiction. This concept contrasts with the concept of a common liability to addiction that involves mechanisms and biobehavioral characteristics pertaining to the entire course of drug abuse risk and disorders.

7. Its Psychic or Physiologic Dependence Liability

Under the seventh factor, the Secretary must consider marijuana's psychic or physiological dependence liability.

Psychic or psychological dependence has been shown in response to marijuana's psychoactive effects. Psychoactive responses to marijuana are pleasurable to many humans and are associated with drug-seeking and drug-taking (Maldonado, 2002). Moreover, high levels of psychoactive effects, notably positive reinforcement, are associated with increased marijuana use, abuse, and dependence (Scherrer et al., 2009; Zeiger et al., 2010). Epidemiological data support these findings through 2012 NSDUH statistics that show that of individuals years 12 or older who used marijuana in the past month, an estimated 40.3 percent used marijuana on 20 or more days within the past month. This equates to approximately 7.6 million individuals aged 12 or older who used marijuana on a daily or almost daily basis.

Additionally, the 2013 MTF data report the prevalence of daily marijuana use, defined as use on 20 or more days within the past 30 days, in 8th, 10th, and 12th graders is 1.1 percent, 4.0 percent, and 6.5 percent, respectively.

Tolerance is a state of adaptation where exposure to a drug induces changes that result in a diminution of one or more of the drug's effects over time (American Academy of Pain Medicine, American Pain Society and American Society of Addiction Medicine consensus document, 2001). Tolerance can develop to some, but not all, of marijuana's effects. Specifically, tolerance does not seem to develop in response to many of marijuana's psychoactive effects. This lack of tolerance may relate to electrophysiological data demonstrating that chronic delta^{9}-THC administration does not affect increased neuronal firing in the ventral tegmental area, a region known to play a critical role in drug reinforcement and reward (Wu and French, 2000). In the absence of other abuse indicators, such as rewarding properties, the presence of tolerance or physical dependence does not determine whether a drug has abuse potential.

However, humans can develop tolerance to marijuana's cardiovascular, autonomic, and behavioral effects (Jones et al., 1981). Tolerance to some of marijuana's behavioral effects seems to develop after heavy marijuana use, but not after occasional marijuana use. For instance, following acute administration of marijuana, heavy marijuana users did not exhibit impairments in tracking and attention tasks, as were seen in occasional marijuana users (Ramaekers et al., 2009). Furthermore, a neurophysiological assessment administered through an electroencephalograph (EEG) which measures event-related potentials (ERP) conducted in the same subjects as the previous study, found a corresponding effect in the P100[26] component of ERPs. Specifically, corresponding to performance on tracking and attention tasks, heavy marijuana users showed no changes in P100 amplitudes following acute marijuana administration, although occasional users showed a decrease in P100 amplitudes (Theunissen et al., 2012). A possible mechanism underlying tolerance to marijuana's effects may be the down-regulation of cannabinoid receptors (Hirvonen et al., 2012; Gonzalez et al., 2005; Rodriguez de Fonseca et al., 1994; Oviedo et al., 1993).

Importantly, pharmacological tolerance alone does not indicate a drug's physical dependence liability. In order for physical dependence to exist, evidence of a withdrawal syndrome is needed. Physical dependence is a state of adaptation, manifested by a drug-class specific withdrawal syndrome produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist (*ibid*). Many medications not associated with abuse or addiction can produce physical dependence and withdrawal symptoms after chronic use.

Discontinuation of heavy, chronic marijuana use has been shown to lead to physical dependence and withdrawal symptoms (American Psychiatric Association DSM–V, 2013; Budney and Hughes, 2006; Haney et al., 1999). In heavy, chronic marijuana users, the most commonly reported withdrawal symptoms are sleep difficulties, decreased appetite or weight loss, irritability, anger, anxiety or nervousness, and restlessness. Some less commonly reported withdrawal symptoms are depressed mood, sweating, shakiness, physical discomfort, and chills (Budney and Hughes, 2006; Haney et al., 1999). The occurrence of marijuana withdrawal symptoms in light or non-daily marijuana users has not been established. The American Psychiatric Association's DSM–V (2013) includes a list of symptoms of "cannabis withdrawal." Most marijuana withdrawal symptoms begin within 24–48 hours of discontinuation, peak within 4–6 days, and last for 1–3 weeks. Marijuana withdrawal syndrome has been reported in adolescents and adults admitted for substance abuse treatment.

Based on clinical descriptions, this syndrome appears to be mild compared to classical alcohol and barbiturate withdrawal syndromes, which can include more serious symptoms such as agitation, paranoia, and seizures. Multiple studies comparing marijuana and tobacco withdrawal symptoms in humans demonstrate that the magnitude and time course of the two withdrawal syndromes are similar (Budney et al., 2008; Vandrey et al., 2005, 2008).

8. Whether the Substance Is an Immediate Precursor of a Substance Already Controlled Under This Article

Under the eight factor analysis, the Secretary must consider whether marijuana is an immediate precursor of a controlled substance. Marijuana is not an immediate precursor of another controlled substance.

Recommendation

After consideration of the eight factors discussed above, FDA recommends that marijuana remain in Schedule I of the CSA. NIDA concurs with this scheduling recommendation. Marijuana meets the three criteria for placing a substance in Schedule I of the CSA under 21 U.S.C. 812(b)(l):

(1) Marijuana has a high potential for abuse:

A number of factors indicate marijuana's high abuse potential, including the large number of individuals regularly using marijuana, marijuana's widespread use, and the vast amount of marijuana available for illicit use. Approximately 18.9 million individuals in the United States (7.3 percent of the U.S. population) used marijuana monthly in 2012. Additionally, approximately 4.3 million individuals met diagnostic criteria for marijuana dependence or abuse in the year prior to the 2012 NSDUH survey. A 2013 survey indicates that by 12th grade, 36.4 percent of students report using marijuana within the past year, and 22.7 percent report using marijuana monthly. In 2011, 455,668 ED visits were marijuana-related, representing 36.4 percent of all illicit drug-related episodes. Primary marijuana use accounted for 18.1 percent of admissions to drug treatment programs in 2011. Additionally, marijuana has dose-dependent reinforcing effects, as demonstrated by data showing that humans prefer relatively higher doses to lower doses. Furthermore, marijuana use can result in psychological dependence.

(2) Marijuana has no currently accepted medical use in treatment in the United States:

FDA has not approved a marketing application for a marijuana drug product for any indication. The opportunity for scientists to conduct clinical research with marijuana exists, and there are active INDs for marijuana; however, marijuana does not have a currently accepted medical use for treatment in the United States, nor does marijuana have an accepted medical use with severe restrictions.

A drug has a "currently accepted medical use" if all of the following five elements have been satisfied:

a. the drug's chemistry is known and reproducible;

b. there are adequate safety studies;

c. there are adequate and well-controlled studies proving efficacy;

d. the drug is accepted by qualified experts; and

e. the scientific evidence is widely available.

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[26] The P100 component of ERPs is thought to relate to the visual processing of stimuli and can be modulated by attention.

[57 FR 10499, March 26, 1992]

Marijuana does not meet any of the elements for having a "currently accepted medical use."

First, FDA broadly evaluated marijuana, and did not focus its evaluation on particular strains of marijuana or components or derivatives of marijuana. Since different strains may have different chemical constituents, marijuana, as identified in this petition, does not have a known and reproducible chemistry, which would be needed to provide standardized doses.

Second, there are not adequate safety studies on marijuana in the medical literature in relation to a specific, recognized disorder. Third, there are no published adequate and well controlled studies proving efficacy of marijuana. Fourth, there is no evidence that qualified experts accept marijuana for use in treating a specific, recognized disorder. Lastly, the scientific evidence regarding marijuana's chemistry in terms of a specific *Cannabis* strain that could produce standardized and reproducible doses is not currently available, so the scientific evidence on marijuana is not widely available.

Alternately, a Schedule II drug can be considered to have a "currently accepted medical use with severe restrictions" (21 U.S.C. 812(b)(2)(B)). Yet as stated above, the lack of accepted medical use for a specific, recognized disorder precludes the use of marijuana even under conditions where its use is severely restricted.

In conclusion, to date, research on marijuana's medical use has not developed to the point where marijuana is considered to have a "currently accepted medical use" or a "currently accepted medical use with severe restrictions."

(3) There is a lack of accepted safety for use of marijuana under medical supervision:

There are currently no FDA-approved marijuana drug products. Marijuana does not have a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions. Thus, FDA has not determined that marijuana is safe for use under medical supervision.

In addition, FDA cannot conclude that marijuana has an acceptable level of safety relative to its effectiveness in treating a specific, recognized disorder without evidence that the substance is contamination free, and assurance of a consistent and predictable dose. Investigations into the medical use of marijuana should include information and data regarding the chemistry, manufacturing, and specifications of marijuana. Additionally, a procedure for delivering a consistent dose of marijuana should also be developed. Therefore, FDA concludes marijuana does not currently have an accepted level of safety for use under medical supervision.

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The Medical Application of Marijuana: A Review of Published Clinical Studies

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Executive Summary

Marijuana is a Schedule I substance under the Controlled Substances Act (CSA). Schedule I indicates a high potential for abuse, no currently accepted medical use in the United States, and a lack of accepted safety for use under medical supervision. To date, marijuana has not been subject to an approved new drug application (NDA) that demonstrates its safety and efficacy for a specific indication under the Food Drug and Cosmetic Act (FDCA).

Nevertheless, as of October 2014, twenty-three states and the District of Columbia have passed state-level medical marijuana laws that allow for marijuana use within that state; similar bills are pending in other states.

The present review was undertaken by the Food and Drug Administration (FDA) to analyze the clinical studies published in the medical literature investigating the use of marijuana in any therapeutic areas. First, we discuss the context for this scientific review. Next, we describe the methods used in this review to identify adequate and well-controlled studies evaluating the safety and efficacy of marijuana for particular therapeutic uses.

The FDA conducted a systematic search for published studies in the medical literature that meet the described criteria for study design and outcome measures prior to February 2013. While not part of our systematic review, we have continued to routinely follow the literature beyond that date for subsequent studies. Studies were considered to be relevant to this review if the investigators administered marijuana to patients with a diagnosed medical condition in a well-controlled, double-blind, placebo-controlled clinical trial. Of the eleven studies that met the criteria for review, five different therapeutic areas were investigated:

- Five studies examined chronic neuropathic pain
- Two studies examined appetite stimulation in human immunodeficiency virus (HIV) patients
- Two studies examined glaucoma
- One study examined spasticity and pain in multiple sclerosis (MS)
- One study examined asthma.

For each of these eleven clinical studies, information is provided regarding the subjects studied, the drug conditions tested (including dose and method of administration), other drugs used by subjects during the study, the physiological and subjective measures collected, the outcome of these measures comparing treatment with marijuana to placebo, and the reported and observed adverse events. The conclusions drawn by the investigators are then described, along with potential limitations of these conclusions based on the study design. A brief summary of each study's findings and limitations is provided at the end of the section.

The eleven clinical studies that met the criteria and were evaluated in this review showed positive signals that marijuana may produce a desirable therapeutic outcome, under the specific experimental conditions tested. Notably, it is beyond the scope of this review to determine whether these data demonstrate that marijuana has a currently accepted medical use in the United States. However, this review concludes that these eleven clinical studies serve as proof-of-concept studies, based on the limitations of their study designs, as described in the study summaries. Proof-of-concept studies provide preliminary evidence on a proposed hypothesis regarding a drug's effect. For drugs under development, the effect often relates to a short-term clinical outcome being investigated. Proof-of-concept studies serve as the link between preclinical studies and dose ranging clinical studies. Therefore, proof-of-concept studies are not sufficient to demonstrate efficacy of a drug because they provide only preliminary information about the effects of a drug. However, the studies reviewed produced positive results, suggesting marijuana should be further evaluated as an adjunct treatment for neuropathic pain, appetite stimulation in HIV patients, and spasticity in MS patients.

The main limitations identified in the eleven studies testing the medical applications of marijuana are listed below:

- The small numbers of subjects enrolled in the studies, which limits the statistical analyses of safety and efficacy.
- The evaluation of marijuana only after acute administration in the studies, which limits the ability to determine efficacy following chronic administration.
- The administration of marijuana typically through smoking, which exposes ill patients to combusted material and introduces problems with determining the doses delivered.
- The potential for subjects to identify whether they received marijuana or placebo, which breaks the blind of the studies.
- The small number of cannabinoid naïve subjects, which limits the ability to determine safety and tolerability in these subjects.
- The low number of female subjects, which makes it difficult to generalize the study findings to subjects of both genders.

Thus, this review discusses the following methodological changes that may be made in order to resolve these limitations and improve the design of future studies which examine the safety and efficacy of marijuana for specific therapeutic indications:

- Determine the appropriate number of subjects studied based on recommendations in various FDA *Guidances for Industry* regarding the conduct of clinical trials for specific medical indications.
- Administer consistent and reproducible doses of marijuana based on recommendations in the FDA *Guidance for Industry: Botanical Drug Products (2004).*[27]
- Evaluate the effects of marijuana under therapeutic conditions following both acute and chronic administration.
- Consider alternatives to smoked marijuana (*e.g.*, vaporization).
- Address and improve whenever possible the difficulty in blinding of marijuana and placebo treatments in clinical studies.
- Evaluate the effect of prior experience with marijuana with regard to the safety and tolerability of marijuana.
- Strive for gender balance in the subjects used in studies.

In conclusion, the eleven clinical studies conducted to date do not meet the criteria required by the FDA to determine if marijuana is safe and effective in specific therapeutic areas. However, the studies can serve as proof-of-concept studies and support further research into the use of marijuana in these therapeutic indications. Additionally, the clinical outcome data and adverse event profiles reported in these published studies can beneficially inform how future research in this area is conducted. Finally, application of the recommendations listed above by investigators when designing future studies could greatly improve the available clinical data that can be used to determine if marijuana has validated and reliable medical applications.

1. Introduction

In response to citizen petitions submitted to the Drug Enforcement Administration (DEA) requesting DEA to reschedule marijuana, the DEA Administrator requested that the U.S. Department of Health and Human

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[27] This Guidance is available on the internet at *http://www.fda.gov/Drugs/default.htm* under Guidance (Drugs).

Services (HHS) provide a scientific and medical evaluation of the available information and a scheduling recommendation for marijuana, in accordance with 21 U.S.C. 811(b). The Secretary of HHS is required to consider in a scientific and medical evaluation eight factors determinative of control under the Controlled Substance Act (CSA). Administrative responsibilities for evaluating a substance for control under the CSA are performed by the Food and Drug Administration (FDA), with the concurrence of the National Institute on Drug Abuse (NIDA). Part of this evaluation includes an assessment of whether marijuana has a currently accepted medical use in the United States. This assessment necessitated a review of the available data from published clinical studies to determine whether there is adequate scientific evidence of marijuana's effectiveness.

Under Section 202 of the CSA, marijuana is currently controlled as a Schedule I substance (21 U.S.C. 812). Schedule I includes those substances that have a high potential for abuse, have no currently accepted medical use in treatment in the United States, and lack accepted safety for use under medical supervision (21 U.S.C. § 812(b)(1)(A)–(C)).

A drug product which has been approved by FDA for marketing in the United States is considered to have a "currently accepted medical use." Marijuana is not an FDA-approved drug product, as a New Drug Application (NDA) or Biologics License application (BLA) for marijuana has not been approved by FDA. However, FDA approval of an NDA is not the only means through which a drug can have a currently accepted medical use in the United States.

In general, a drug may have a "currently accepted medical use" in the United States if the drug meets a five-part test. Established case law (*Alliance for Cannabis Therapeutics* v. *DEA,* 15 F.3d 1131, 1135 (D.C. Cir. 1994)) upheld the Administrator of DEA's application of the five-part test to determine whether a drug has a "currently accepted medical use." The following describes the five elements that characterize "currently accepted medical use" for a drug:[28]

i. the drug's chemistry must be known and reproducible.

"The substance's chemistry must be scientifically established to permit it to be reproduced into dosages which can be standardized. The listing of the substance in a current edition of one of the official compendia, as defined by section 201(j) of the Food, Drug and Cosmetic Act, 21 U.S.C. 321(j), is sufficient to meet this requirement."

ii. there must be adequate safety studies.

"There must be adequate pharmacological and toxicological studies, done by all methods reasonably applicable, on the basis of which it could fairly and responsibly be concluded, by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, that the substance is safe for treating a specific, recognized disorder."

iii. there must be adequate and well-controlled studies proving efficacy.

"There must be adequate, well-controlled, well-designed, well-conducted, and well-documented studies, including clinical investigations, by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, on the basis of which it could be fairly and responsibly concluded by such experts that the substance will have the intended effect in treating a specific, recognized disorder."

iv. the drug must be accepted by qualified experts.

"The drug has a New Drug Application (NDA) approved by the Food and Drug Administration, pursuant to the Food, Drug and Cosmetic Act, 21 U.S.C. 355. Or, a consensus of the national community of experts, qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, accepts the safety and effectiveness of the substance for use in treating a specific, recognized disorder. A material conflict of opinion among experts precludes a finding of consensus." and

v. the scientific evidence must be widely available.

"In the absence of NDA approval, information concerning the chemistry, pharmacology, toxicology, and effectiveness of the substance must be reported, published, or otherwise widely available, in sufficient detail to permit experts, qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, to fairly and responsibly conclude the substance is safe and effective for use in treating a specific, recognized disorder."

One way to pass the five-part test for having "currently accepted medical use" is through submission of an NDA or BLA which is approved by FDA. However, FDA approval of an NDA or BLA is not required for a drug to pass the five-part test.

This review focuses on FDA's analysis of one element of the five-part test for determining whether a drug has "currently accepted medical use". Specifically, the present review assesses the 3rd criterion that addresses whether marijuana has "adequate and well-controlled studies proving efficacy". Thus, this review evaluates published clinical studies that have been conducted using marijuana in subjects who have a variety of medical conditions by assessing the adequacy of the summarized study designs and the study data. The methodology for selecting the studies that were evaluated is delineated below.

FDA's evaluation and conclusions regarding the remaining four criteria for whether marijuana has a "currently accepted medical use," as well as the eight factors pertaining to the scheduling of marijuana, are outside the scope of this review. A detailed discussion of these factors is contained in FDA's scientific and medical evaluation of marijuana.

2. Methods

The methods for selecting the studies to include in this review involved the following steps, which are described in detail in the subsections below:

1. Define the objective of the review.
2. Define "marijuana" in order to facilitate the medical literature search for studies that administered the substance,
3. Define "adequate and well-controlled studies" in order to facilitate the search for relevant data and literature,
4. Search medical literature databases and identify relevant adequate and well-controlled studies, and
5. Review and analyze the adequate and well-controlled clinical studies to determine if they demonstrate efficacy of marijuana for any therapeutic indication.

2.1 Define the Objective of the Review

The objective of this review is to assess the study designs and resulting data from clinical studies published in the medical literature that were conducted with marijuana (as defined below) as a treatment for any therapeutic indication, in order to determine if they meet the criteria of "adequate and well-controlled studies proving efficacy".

2.2 Define "Marijuana"

In this review, the term "marijuana" refers to the flowering tops or leaves of the *Cannabis* plant. There were no restrictions on the route of administration used for marijuana in the studies.

Studies which administered individual cannabinoids (whether experimental substances or marketed drug products) or marijuana extracts were excluded from this review. Additionally, studies of administered neutral plant material or placebo marijuana (marijuana with all cannabinoids extracted) that had subsequently been supplemented by the addition of specific amounts of THC or other cannabinoids were also excluded (Chang et al., 1979).

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[28] 57 FR 10499, 10504–06 (March 26, 1992).

2.3 Define "Adequate and Well-Controlled Clinical Studies"

The criteria for an "adequate and well-controlled study" for purposes of determining the safety and efficacy of a human drug is defined under the Code of Federal Regulations (CFR) in 21 CFR 314.126. The elements of an adequate and well-controlled study as described in 21 CFR 314.126 can be summarized as follows:

1. The main objective must be to assess a therapeutically relevant outcome.
2. The study must be placebo-controlled.
3. The subjects must qualify as having the medical condition being studied.
4. The study design permits a valid comparison with an appropriate control condition.
5. The assignment of subjects to treatment and control groups must be randomized.
6. There is minimization of bias through the use of a double-blind study design.
7. The study report contains a full protocol and primary data.
8. Analysis of the study data is appropriately conducted.

As noted above, the current review examines only those data available in the public domain and thus relies on clinical studies published in the medical literature. Published studies by their nature are summaries that do not include the level of detail required by studies submitted to FDA in an NDA.

While the majority of the elements defining an adequate and well-controlled study can be satisfied through a published paper (elements #1–6), there are two elements that cannot be met by a study published in the medical literature: element #7 (availability of a study report with full protocol and primary data) and element #8 (a determination of whether the data analysis was appropriate). Thus, for purposes of this review, only elements #1–6 will be used to qualify a study as being adequate and well-controlled.

2.4 Search Medical Literature Databases and Identify Relevant Studies

We identified randomized, double-blind, placebo-controlled clinical studies conducted with marijuana to assess marijuana's efficacy in any therapeutic indication. Two primary medical literature databases were searched for all studies posted to the databases prior to February 2013:[29]

- *PubMed:* PubMed is a database of published medical and scientific studies that is maintained by the U.S. National Library of Medicine (NLM) at NIH as a part of the Entrez system of information retrieval. PubMed comprises more than 24 million citations for biomedical literature from MEDLINE, life science journals, and online books (*http://www.ncbi.nlm.nih.gov/pubmed*).
- *ClinicalTrials.gov:* ClinicalTrials.gov is a database of publicly and privately supported clinical studies that is maintained by the NLM. Information about the clinical studies is provided by the Sponsor or Principal Investigator of the study. Information about the studies is submitted to the Web site ("registered") when the studies begin, and is updated throughout the study. In some cases, results of the study or resulting publication citations are submitted to the Web site after the study ends (*https://clinicaltrials.gov/ct2/about-site/background*).

ClinicalTrials.gov was searched for all studies administering marijuana. The results of this search were used to confirm that no completed studies with published data were missed in the literature search. During the literature search, references found in relevant studies and systematic reviews were evaluated for additional relevant citations. All languages were included in the search. The PubMed search yielded a total of 566 abstracts.[30] Of these abstracts, a full-text review was conducted with 85 papers to assess eligibility. From this evaluation, only eleven of 85 studies met the 6 CFR elements for inclusion as adequate and well-controlled studies.

Figure 1 (below) provides an overview of the process used to identify studies from the PubMed search. The eleven studies reviewed were published between 1974 and 2013. Ten of these studies were conducted in the United States and one study was conducted in Canada. These eleven studies examined the effects of smoked and vaporized marijuana for the indications of chronic neuropathic pain, spasticity related to multiple sclerosis (MS), appetite stimulation in patients with human immunodeficiency virus (HIV), glaucoma, and asthma. All included studies used adult patients as subjects. All studies conducted in the United States were conducted under an IND as Phase 2 investigations.

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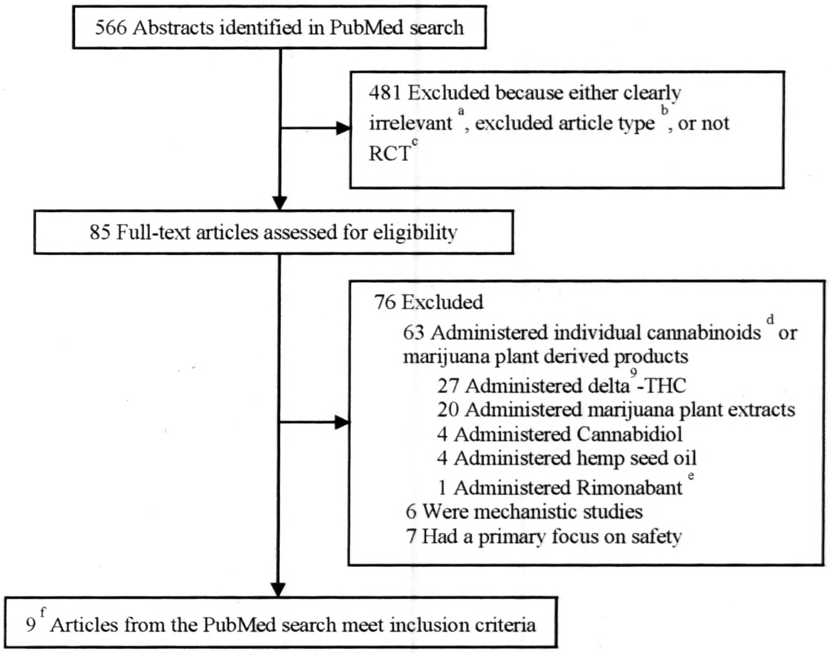
[29] While not a systematic review, we have followed the recent published literature on marijuana use for possible therapeutic purposes and, as of January 2015, we found only one new study that would meet our criteria (Naftali et al., 2013). This study examined the effects of smoked marijuana on Crohn's disease.

[30] The following search strategy was used, "(cannabis OR marijuana) AND (therapeutic use OR therapy) AND (RCT OR randomized controlled trial OR "systematic review" OR clinical trial OR clinical trials) NOT ("marijuana abuse" [Mesh] OR addictive behavior OR substance related disorders)".

Figure 1: Identification of Studies from PubMed Search


566 Abstracts identified in PubMed search
481 Excluded because either clearly irrelevant [a], excluded article type [b], or not RCT[c]
85 Full-text articles assessed for eligibility
76 Excluded
63 Administered individual cannabinoids [d] or marijuana plant derived products
27 Administered delta^9-THC
20 Administered marijuana plant extracts
4 Administered Cannabidiol
4 Administered hemp seed oil
1 Administered Rimonabant [e]
6 Were mechanistic studies
7 Had a primary focus on safety
9 [f] Articles from the PubMed search meet inclusion criteria

[a]Articles were deemed irrelevant if they examined safety or adverse event related outcomes, including psychoactive effects or other adverse events. [b]Excluded article types included comments, reviews, meta-analyses, and news articles. [c]Randomized Controlled Trials. [d]Cannabinoids administered included synthetic cannabinoids. [e]Rimonabant is a cannabinoid receptor antagonist. [f]An additional 2 studies meeting the inclusion criteria were found through

Two qualifying studies, which assessed marijuana for glaucoma, were previously reviewed in the 1999 Institute of Medicine (IOM) report entitled "Marijuana and Medicine: Assessing the Science Base".[31] We did our own analysis of these two studies and concurred with the conclusions in the IOM report. Thus, a detailed discussion of the two glaucoma studies is not included in the present review. The present review only discusses 9 of the identified 11 studies. For a summary of the study design for all eleven qualifying studies, see Tables 1–5 (located in the Appendix).

Based on the selection criteria for relevant studies described in Section 2.3 (Define Adequate and Well-Controlled Clinical Studies), a number of clinical studies that investigated marijuana, as defined in this review, were excluded from this review. Studies that examined the effects of marijuana in healthy subjects were excluded because they did not test a patient population with a medical condition (Flom et al., 1975; Foltin et al., 1986; Foltin et al., 1988; Hill et al., 1974; Milstein et al., 1974; Milstein et al., 1975; Soderpalm et al., 2001; Wallace et al., 2007; Greenwald and Stitzer, 2000). A 1975 study by Tashkin et al. was excluded because it had a single-blind, rather than double-blind, study design. Two other studies were excluded because the primary outcome measure assessed safety rather than a therapeutic outcome (Greenberg et al., 1994; Abrams et al., 2003).

2.5 Review and Analyze Qualifying Clinical Studies

Qualified clinical studies that evaluated marijuana for therapeutic purposes were examined in terms of adequacy of study design including method of drug administration, study size, and subject inclusion and exclusion criteria. Additionally, the measures and methods of analysis used in the studies to assess the treatment effect were examined.

3. Results and Discussion

The eleven qualifying studies in this review assessed a variety of therapeutic indications. In order to better facilitate analysis and discussion of the studies, the following sections group the studies by therapeutic area. Within each section, each individual study is summarized in terms of its design, outcome data and important limitations. This information is also provided in the Appendix in tabular form for each study.

3.1 Neuropathic Pain

Five randomized, double-blind, placebo-controlled Phase 2 clinical studies have been conducted to examine the effects of inhaled marijuana smoke on neuropathic pain associated with HIV-sensory neuropathy (Abrams et al., 2007; Ellis et al., 2009) and chronic neuropathic pain from multiple causes (Wilsey et al., 2008; Ware et al., 2010; Wilsey et al., 2013). Table 1 of the Appendix summarizes these studies.

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[31] In January 1997, the White House Office of National Drug Control Policy (ONDCP) requested that the IOM conduct a review of the scientific evidence to assess the potential health benefits and risks of marijuana and its constituent cannabinoids. Information for this study was gathered through scientific workshops, site visits to cannabis buyers' clubs and HIV/Acquired Immunodeficiency Syndrome (AIDS) clinics, analysis of the relevant scientific literature, and extensive consultation with biomedical and social scientists. The report was finalized and published in 1999.

3.1.1 Neuropathic Pain Associated with HIV-Sensory Neuropathy

Two studies examined the effect of marijuana to reduce the pain induced by HIV-sensory neuropathy.

Abrams et al. (2007) conducted the first study entitled, "Cannabis in painful HIV-associated sensory neuropathy: A randomized placebo-controlled trial". The subjects were 50 adult patients with uncontrolled HIV-associated sensory neuropathy, who had at least 6 experiences with smoking marijuana. The subjects were split into two parallel groups of 25 subjects each. More than 68% of subjects were current marijuana users, but all individuals were required to discontinue using marijuana prior to the study. Most subjects were taking medication for pain during the study, with the most common medications being opioids and gabapentin. Upon entry into the study, subjects had an average daily pain score of at least 30 on a 0–100 visual analog scale (VAS).

Subjects were randomized to receive either smoked marijuana (3.56% THC[32]) or smoked placebo cigarettes three times per day for 5 days, using a standardized cued smoking procedure: (1) 5 second inhale, (2) 10 second holding smoke in the lungs, (3) 40 second exhale and breathing normally between puffs. The authors did not specify how many puffs the subjects smoked at each smoking session, but they stated that one cigarette was smoked per smoking session.

Primary outcome measures included daily VAS ratings of chronic pain and the percentage of subjects who reported a result of more than 30% reduction in pain intensity. The ability of smoked marijuana to induce acute analgesia was assessed using both thermal heat model and capsaicin sensitization model, while anti-hyperalgesia was assessed with brush and von Frey hair stimuli. The immediate analgesic effects of smoked marijuana was assessed using a 0–100 point VAS at 40-minute intervals three times before and three times after the first and last smoking sessions, which was done to correspond to the time of peak plasma cannabinoid levels. Notably, not all subjects completed the induced pain portion of the study (n = 11 in marijuana group, 9 in placebo group) because of their inability to tolerate the stimuli. Throughout the study, subjects also completed the Profile of Mood States (POMS) questionnaire, as well as subjective VAS measures of anxiety, sedation, disorientation, paranoia, confusion, dizziness, and nausea.

As a result, the median daily pain was reduced 34% by smoked marijuana compared to 17% by placebo ($p = 0.03$). Fifty-two percent of subjects who smoked marijuana reported a >30% reduction in pain compared to 24% in the placebo group ($p = 0.04$). Although marijuana reduced experimentally-induced hyperalgesia ($p \leq 0.05$) during the first smoking sessions, marijuana did not alter responses to acutely painful stimuli.

There were no serious AEs and no episodes of hypertension, hypotension, or tachycardia requiring medical intervention. No subjects withdrew from the study for drug related reasons. Subjects in the marijuana group reported higher ratings on the subjective measures of anxiety, sedation, disorientation, confusion, and dizziness compared to the placebo group. There was one case of severe dizziness in a marijuana-treated subject. By the end of the study, subjects treated with marijuana and placebo reported a reduction in total mood disturbance as measured by POMS.

The authors conclude that smoked marijuana effectively reduced chronic neuropathic pain from HIV-associated sensory neuropathy with tolerable side effects. However, limitations of this study include: maintenance of subjects on other analgesic medication while being tested with marijuana and a lack of information about the number of puffs during each inhalation of smoke. These limitations make it difficult to conclude that marijuana has analgesic properties on its own and that the actual AEs experienced during the study in response to marijuana are tolerable. However, the study produced positive results suggesting that marijuana should be studied further as an adjunct treatment for uncontrolled HIV-associated sensory neuropathy.

Ellis et al. (2009) conducted a more recent study entitled "Smoked medicinal cannabis for neuropathic pain in HIV: A randomized, crossover clinical trial". The subjects were 28 HIV-positive adult male patients with intractable neuropathic pain that was refractory to the effects of at least two drugs taken for analgesic purposes. Upon entry into the study, subjects had a mean score of >5 on the Pain Intensity subscale of the Descriptor Differential Scale (DDS). Subjects were allowed to continue taking their current routine of pain medications, which included opioids, non-narcotic analgesics, antidepressants, and anticonvulsants. Previous experience with marijuana was not required for participation in the study, but 27 of 28 subjects (96%) reported previous experience with marijuana. However, of these 27 experienced subjects, 63% (n = 18) reported no marijuana use within the past year.

The study procedures compared the effects of the target dose of marijuana and placebo during two treatment periods lasting 5 days, with 2 weeks washout periods. The marijuana strengths available were 1%, 2%, 4%, 6%, or 8% THC concentration by weight. Subjects smoked marijuana or placebo cigarettes four times per day, approximately 90–120 minutes apart, using a standardized cued smoking procedure: (1) 5 second smoke inhalation, (2) 10 second hold of smoke in lungs, (3) 40 second exhale and normal breathing between puffs. The investigators did not provide a description of the number of puffs taken at any smoking session. All subjects practiced the smoking procedures using placebo marijuana prior to test sessions.

On the first day of each test period, dose titration occurred throughout the four smoking sessions scheduled for that day, with a starting strength of 4% THC concentration. Subjects were allowed to titrate to a personalized "target dose", which was defined as the dose that provided the best pain relief without intolerable adverse effects. This dose titration was accomplished by allowing subjects to either increase the dose incrementally (to 6% or 8% THC) to improve analgesia, or to decrease the dose incrementally (to 1% or 2% THC) if AEs were intolerable. For the next 4 days of each test period, the subjects smoked their target dose during each of the four daily smoking sessions. To maintain the blind, placebo marijuana was represented as containing 1%-8% THC, even though it did not contain any cannabinoids.

The primary outcome measure was the change in pain magnitude on the DDS at the end of each test period compared to baseline, with a clinically significant level of analgesia considered to be a reduction in pain of at least 30%. Additional measures included the POMS, the Sickness Impact Profile (SIP), the Brief Symptom Inventory (BSI) and the UKU Side Effect Rating Scale and a subjective highness/sedation VAS.

During the marijuana treatment week, 19 subjects titrated to the 2%–4% THC dose while the 6%–8% dose was preferred by 8 subjects and 1 subject chose the 1% dose. In contrast, during the placebo treatment week, all 28 subjects titrated to the highest possible dose of "8% THC" that contained no actual cannabinoids, suggesting that placebo treatment provided little analgesic relief.

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[32] The drug dose is reported as percentage of THC present in the marijuana rather than milligrams of THC present in each cigarette because of the difficulty in determining the amount of THC delivered by inhalation (see discussion in the section entitled "3.7.2 Marijuana Dose Standardization").

The degree of pain reduction was significantly greater after administration of marijuana compared to placebo (median change of 3.3 points on DDS, $p = 0.016$). The median change from baseline in VAS pain scores was −17 for marijuana treatment compared to −4 for placebo treatment ($p < 0.001$). A larger proportion of subjects who were treated with marijuana (0.46) reported a >30% reduction in pain, compared to placebo (0.18). Additionally, the authors report improvements in total mood disturbance, physical disability, and quality of life as measured on POMS, SIP, and BSI scales after both placebo and marijuana treatment (data not provided in paper).

In terms of safety, there were no alterations in HIV disease parameters in response to marijuana or placebo. The authors report that marijuana led to a greater degree of UKU responses as well as AEs such as difficulty in concentration, fatigue, sleepiness or sedation, increased duration of sleep, reduced salivation and thirst compared to placebo (data not provided in paper). Two subjects withdrew from the study because of marijuana-related AEs: one subject developed an intractable smoking-related cough during marijuana administration and the sole marijuana-naïve subject in the study experienced an incident of acute cannabis-induced psychosis.[33]

The authors conclude that smoked marijuana effectively reduced chronic neuropathic pain from HIV-associated sensory neuropathy. The limitations of this study include: a lack of information about the number of puffs during each inhalation of smoke; a lack of information about the specific timing of the subjective assessments and collection of AEs relative to initiation of the smoking sessions; and the inclusion of only one marijuana-naïve subject. These limitations make it difficult to conclude that the actual AEs experienced during the study in response to marijuana are tolerable. It is especially concerning that the only marijuana-naïve subject left the study because of serious psychiatric responses to marijuana exposure at analgesic doses. However, the study produced positive results suggesting that marijuana should be studied further as an adjunct treatment for uncontrolled HIV-associated sensory neuropathy.

3.1.2 Central and Peripheral Neuropathic Pain

Three studies examined the effect of marijuana on chronic neuropathic pain.

Wilsey et al. (2008) examined chronic neuropathic pain from multiple causes in the study entitled, "A Randomized, Placebo-Controlled, Crossover Trial of Cannabis Cigarettes in Neuropathic Pain". The subjects were 32 patients with a variety of neuropathic pain conditions, including 22 with complex regional pain syndrome, 6 with spinal cord injury, 4 with multiple sclerosis, 3 with diabetic neuropathy, 2 with ilioinguinal neuralgia, and 1with lumbosacral plexopathy. All subjects reported a pain intensity of at least 30 on a 0–100 VAS and were allowed to continue taking their regular medications during the study period, which included opioids, antidepressants, anticonvulsants, and NSAIDs. All subjects were required to have experience with marijuana but could not use any cannabinoids for 30 days before study sessions.

The study consisted of three test sessions with an interval of 3–21 days between sessions. Treatment conditions were high-strength marijuana (7% delta-9–THC), low-strength marijuana (3.5% delta-9–THC), and placebo cigarettes, administered through a standardized cued-puff procedure: (1) "light the cigarette" (30 seconds), (2) "get ready" (5 seconds), (3) "inhale" (5 seconds), (4) "hold smoke in lungs" (10 seconds), (5) "exhale," and (6) wait before repeating the puff cycle (40 seconds). Participants took 2 puffs after baseline measurements, 3 puffs an hour later, and 4 puffs an hour after that, for a cumulative dose of 9 puffs per test session.

Hourly assessment periods were scheduled before and after each set of puffs and for 2 additional hours during the recovery period. Plasma cannabinoids were measured at baseline, 5 minutes after the first puff and again at 3 hours after the last puff cycle.

The primary outcome measure was spontaneous pain relief, as measured by a 0–100 point VAS for current pain. Pain unpleasantness was measured on a 0–100 point VAS, and degree of pain relief was measured on a 7-point Patient Global Impression of Change (PGIC) scale. Secondary measures included the Neuropathic Pain Scale (NPS), a 0–100 point VAS for allodynia, and changes in thermal pain threshold. Subjective measures were also evaluated with unipolar 0–100 point VAS for any drug effect, good drug effect, bad drug effect, high, drunk, impaired, stoned, like the drug effect, sedated, confused, nauseated, desire more of the drug, anxious, down, hungry, and bipolar 0–100 point VAS for sad/happy, anxious/relaxed, jittery/calm, bad/good, paranoid/self-assured, fearful/unafraid. Neurocognitive assessments measured attention and concentration, learning and memory, and fine motor speed.

Marijuana produced a reduction in pain compared to placebo, as measured by the pain VAS, the PGIC and on pain descriptors in the NPS, including sharp ($P < .001$), burning ($P < .001$), aching ($P < .001$), sensitive ($P = .03$), superficial ($P < .01$) and deep pain ($P < .001$). Notably, there were no additional benefits from the 7% THC strength of marijuana compared to the 3.5% THC strength, seemingly because of cumulative drug effects over time. There were no changes in allodynia or thermal pain responsivity following administration of either dose of marijuana.

Marijuana at both strengths produced increases on measures of any drug effect, good drug effect, high, stoned, impairment, sedation, confusion, and hunger. The 7% THC marijuana increased anxiety scores and bad drug effect (later in session) compared to placebo. Neither strength of marijuana affected the measures of mood. On neurocognitive measures, both the 3.5% THC and 7% THC marijuana produced impairment in learning and memory, while only the 7% THC marijuana impaired attention and psychomotor speed, compared to placebo. There were no adverse cardiovascular side effects and no subjects dropped out because of an adverse event related to marijuana.

The authors conclude that marijuana may be effective at ameliorating neuropathic pain at doses that induce mild cognitive effects, but that smoking is not an optimum route of administration. The limitations of this study include: inclusion of subjects with many forms of neuropathic pain and maintenance of subjects on other analgesic medication while being tested with marijuana. These limitations make it difficult to conclude that marijuana has analgesic properties on its own and that the actual AEs experienced during the study in response to marijuana are tolerable. The authors compared pain score results by the type of pain condition, with no significant differences found; however, the sample size of this study was small thus a type II error may have been present. Thus, it is difficult to determine if any particular subset of neuropathic pain conditions would benefit specifically from marijuana administration. However, the study produced positive results suggesting that marijuana should be studied further as an adjunct treatment for uncontrolled neuropathic pain.

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[33] At the time of the study, the following criteria from the Diagnostic and Statistical Manual of Mental Disorders (DSM–IV–TR, 2000) were used to diagnose substance-induced psychotic disorders: Prominent hallucinations or delusions; Hallucinations and/or delusions that develop during, or within one month of, intoxication or withdrawal; The disturbance is not better accounted for by a psychotic disorder that is not substance induced. The disturbance does not occur exclusively during the course of a delirium.

The second study, conducted by Ware et al. (2010) in Canada is entitled, "Smoked cannabis for chronic neuropathic pain: a randomized controlled trial". The subjects were 21 adult patients with neuropathic pain caused by trauma or surgery compounded with allodynia or hyperalgesia, and a pain intensity score greater than 4 on a 10 point VAS. All subjects maintained their current analgesic medication and they were allowed to use acetaminophen for breakthrough pain. Eighteen subjects had previous experience with marijuana but none of them had used marijuana within a year before the study.

The study design used a four-period crossover design, testing marijuana (2.5%, 6.0% and 9.4% THC) and placebo marijuana. The 2.5% and 6.0% doses of marijuana were included to increase successful blinding. Each period was 14 days in duration, beginning with 5 days on the study drug followed by a 9-day washout period. Doses were delivered as 25 mg of marijuana that was smoked in a single inhalation using a titanium pipe. The first dose of each period was self-administered using a standardized puff procedure: (1) Inhale for 5 seconds, (2) hold the smoke in their lungs for 10 seconds, and (3) exhale. Subsequent doses were self-administered in the same manner for a total of three times daily at home on an outpatient basis for the first five days of each period.

The primary measure was an 11-point pain intensity scale, averaged over the 5 day treatment period, which was administered once daily for present, worst, least and average pain intensity during the previous 24 hours. Secondary measures included an acute pain 0–100 point VAS, pain quality assessed with the McGill Pain Questionnaire, sleep assessed with the Leeds Sleep Evaluation Questionnaire, mood assessed with the POMS, quality of life assessed using the EQ–5D health outcome instrument. Subjective measures included 0–100 point VAS scales for high, relaxed, stressed and happy.

Over the first three hours after smoking marijuana, ratings of pain, high, relaxation, stress, happiness and heart rate were recorded. During the five days of each study period, participants were contacted daily to administer questionnaires on pain intensity, sleep, medication and AEs. Subjects returned on the fifth day to complete questionnaires on pain quality, mood, quality of life and assessments of potency. At the end of the study, participants completed final adverse event reports and potency assessments.

The average daily pain intensity was significantly lower on 9.4% THC marijuana (5.4) than on placebo marijuana (6.1) ($p = 0.023$). The 9.4% THC strength also produced more drowsiness, better sleep, with less anxiety and depression, compared to placebo (all $p < 0.05$). However, there were no significant differences on POMS scores or on VAS scores for high, happy, relaxed or stressed between THC doses.

The most frequent drug-related adverse events reported in the group receiving 9.4% THC marijuana were headache, dry eyes, burning sensation, dizziness, numbness and cough. Reports of high and euphoria occurred on only three occasions, once in each dose of THC. There were no significant changes in vital signs, heart-rate variability, or renal function. One subject withdrew from the study due to increased pain during administration of 6% THC marijuana.

The authors conclude that smoked marijuana reduces neuropathic pain, improves mood and aids in sleep, but that smoking marijuana is not a preferable route of administration. The limitations of this study include: The lack of information on timing of assessments during the outpatient portion of the study and maintenance of subjects on other analgesic medication while being tested with marijuana. These limitations make it difficult to conclude that marijuana has analgesic properties on its own and that the actual AEs experienced during the study in response to marijuana are tolerable. However, the study produced positive results suggesting that marijuana should be studied further as an adjunct treatment for uncontrolled neuropathic pain.

Wilsey et al. (2013) conducted the most recent study entitled, "Low-Dose Vaporized Cannabis Significantly Improves Neuropathic Pain". This study is the only one in this review that utilized vaporization as a method of marijuana administration. The subjects were 36 patients with a neuropathic pain disorder (CRPS, thalamic pain, spinal cord injury, peripheral neuropathy, radiculopathy, or nerve injury) who were maintained on their current medications (opioids, anticonvulsants, antidepressants, and NSAIDs). Although subjects were required to have a history of marijuana use, they refrained from use of cannabinoids for 30 days before study sessions.

Subjects participated in three sessions in which they received 1.29% or 3.53% THC marijuana or placebo marijuana. The marijuana was vaporized using the Volcano vaporizer and a standardized cued-puff procedure: (1) "hold the vaporizer bag with one hand and put the vaporizer mouthpiece in their mouth" (30 seconds), (2) "get ready" (5 seconds), (3) "inhale" (5 seconds), (4) "hold vapor in lungs" (10 seconds), (5) "exhale and wait" before repeating puff cycle (40 seconds). Subjects inhaled 4 puffs at 60 minutes. At 180 minutes, the vaporizer was refilled with marijuana vapor and subjects were allowed to inhale 4 to 8 puffs using the cued procedure. Thus, cumulative dosing allowed for a range of 8 to12 puffs in total for each session, depending on the subjects desired response and tolerance. The washout time between each session ranged from 3–14 days.

The primary outcome variable was spontaneous pain relief, as assessed using a 0–100 point VAS for current pain. Secondary measures included the Patient Global Impression of Change (PGIC), the Neuropathic Pain Scale (NPS), a 0–100 point VAS for allodynia. Acute pain threshold was measured with a thermal pain model. Subjective measures included 0–100 point unipolar VAS for any drug effect, good drug effect, bad drug effect, high, drunk, impaired, stoned, drug liking, sedated, confused, nauseated, desire more drug, anxious, down and hungry. Bipolar 0–100 point VAS included sad/happy, anxious/relaxed, jittery/calm, bad/good, paranoid/self-assured, and fearful/unafraid. Neurocognitive assessments assessed attention and concentration, learning and memory, and fine motor speed.

A 30% reduction in pain was achieved in 61% of subjects who received the 3.53% THC marijuana, in 57% of subjects who received the 1.29% THC marijuana and in 26% of subjects who received the placebo marijuana ($p = 0.002$ for placebo vs. 3.53% THC, $p = 0.007$ for placebo vs 1.29% THC; $p > 0.05$ 1.29% THC vs. 3.53% THC). Both strengths of marijuana significantly decreased pain intensity, unpleasantness, sharpness, and deepness on the NPS, as well as pain ratings on the PGIC, compared to placebo. These effects on pain were maximal with cumulative dosing over the course of the study session, with maximal effects at 180 minutes. There were no effects of marijuana compared to placebo on measures of allodynia or thermal pain. Subjects correctly identified the study treatment 63% of the time for placebo, 61% of the time for 1.29% THC, and 89% of the time for 3.53% THC.

On subjective measures, marijuana produced dose-dependent increases compared to placebo on ratings for: any drug effect, good drug effect, drug liking, high, stoned, sedated, confused, and hungry. Both strengths of marijuana produced similar increases in drunk or impaired compared to placebo. In contrast, desire for drug was rated as higher for the 1.29% THC marijuana compared to the 3.53% THC marijuana. There were no changes compared to placebo for bad effect, nauseous, anxiety, feeling down or any of the bipolar mood assessments. There was dose-dependent impairment on learning and memory from marijuana compared to placebo, but similar effects between the two strengths of marijuana on attention.

The authors conclude that vaporization of relatively low doses of marijuana can produce improvements in analgesia in neuropathic pain patients, especially when patients are allowed to titrate their exposure. However, this individualization of doses may account for the general lack of difference between the two strengths of marijuana. No data were presented regarding the total amount of THC consumed by each subject, so it is difficult to determine a proper dose-response evaluation. Additional limitations of this study are the inclusion of subjects with many forms of neuropathic pain and maintenance of subjects on other analgesic medication while being tested with marijuana. These limitations make it difficult to conclude that marijuana has analgesic properties on its own. It is also difficult to determine if any particular subset of neuropathic pain conditions would benefit specifically from marijuana administration. However, the study produced positive results suggesting that marijuana should be studied further as an adjunct treatment for uncontrolled neuropathic pain.

3.2 *Appetite Stimulation in HIV*

Two randomized, double-blind, placebo-controlled Phase 2 studies examined the effects of smoked marijuana on appetite in HIV-positive subjects (Haney et al., 2005; Haney et al., 2007). Table 2 of the Appendix summarizes both studies.

The first study, conducted by Haney et al. (2005) is entitled, "Dronabinol and marijuana in HIV+ marijuana smokers: acute effects on caloric intake and mood". The subjects were 30 HIV-positive patients who were maintained on two antiretroviral medications and either had clinically significant decreases in lean muscle mass[34] (low-BIA group, n = 15) or normal lean muscle mass (normal-BIA group, n = 15). All subjects had a history of smoking marijuana at least twice weekly for 4 weeks prior to entry into the study. On average, individuals had smoked 3 marijuana cigarettes per day, 5–6 times per week for 10–12 years.

Subjects participated in 8 sessions that tested the acute effects of 0, 10, 20, and 30 mg dronabinol oral capsules and marijuana cigarettes with 0%, 1.8%, 2.8%, and 3.9% THC concentration by weight, using a double-dummy design (with only one active drug per session). The doses of dronabinol are higher than those doses typically prescribed for appetite stimulation in order to help preserve the blinding. There was a one-day washout period between test sessions.

Marijuana was administered using a standardized cued procedure: (1) "light the cigarette" (30 seconds), (2) "prepare" (5 seconds), (3) "inhale" (5 seconds), (4) "hold smoke in lungs" (10 seconds), and (5) "exhale." Each subject smoked three puffs in this manner, with a 40-second interval between each puff.

Caloric intake was used as a surrogate measure for weight gain. Subjects received a box containing a variety of food and beverage items and were told to record consumption of these items following that day's administration of the test drug. Subjective measures included 0–100 point VAS for feel drug effect, good effect, bad effect, take drug again, drug liking, hungry, full, nauseated, thirsty, desire to eat. Neurocognitive measures and vital signs were monitored.

The low BIA group consumed significantly more calories in the 1.8% and 3.9% THC marijuana conditions ($p < 0.01$) and the 10, 20, and 30 mg dronabinol conditions ($p < 0.01$) compared with the placebo condition. In contrast, in the normal BIA group, neither marijuana nor dronabinol significantly affected caloric intake. This lack of effect may be accountable, however, by the fact that this group consumed approximately 200 calories more than the low BIA group under baseline conditions.

Ratings of high and good drug effect were increased by all drug treatments in both the low-BIA and normal-BIA groups, except in response to the 10 mg dose of dronabinol. The 3.9% THC marijuana increased ratings of good drug effect, drug liking and desire to smoke again compared with placebo. Ratings of sedation were increased in both groups by 10 and 30 mg dronabinol, and in the normal BIA group by the 2.8% THC marijuana. Ratings of stimulation were increased in the normal BIA group by 2.8% and 3.9% THC marijuana and by 20 mg dronabinol. Increases in ratings of forgetfulness, withdrawn, dreaming, clumsy, heavy limbs, heart pounding, jittery, and decreases in ratings of energetic, social, and talkative were reported in the normal BIA group with 30 mg dronabinol. There were no significant changes in vital signs or performance on neurocognitive measures in response to marijuana. Notably, the time course of subjective effects peaked quickly and declined thereafter for smoked marijuana, while oral dronabinol responses took longer to peak and persisted longer. Additionally, marijuana but not dronabinol produced dry mouth and thirst.

In general, AEs reported in this study were low in both drug conditions for both subject groups. In the low BIA group, nausea was reported by one subject in both the 10 and 20 mg dronabinol conditions, while an uncomfortable level of intoxication was produced by the 30 mg dose in two subjects. There were no AEs reported in this group following marijuana at any dose. In the normal BIA group, the 30 mg dose of dronabinol produced an uncomfortable level of intoxication in three subjects and headache in one subject, while the 3.9% marijuana produced diarrhea in one subject.

The authors conclude that smoked marijuana can acutely increase caloric intake in low BIA subjects without significant cognitive impairment. However, it is possible that the low degree of cognitive impairment reported in this study may reflect the development of tolerance to cannabinoids in this patient population, since all individuals had current histories of chronic marijuana use. Additional limitations in this study include not utilizing actual weight gain as a primary measure. However, the study produced positive results suggesting that marijuana should be studied further as a treatment for appetite stimulation in HIV patients.

A second study conducted by Haney et al. (2007) is entitled, "Dronabinol and marijuana in HIV-positive marijuana smokers: Caloric intake, mood, and sleep". The design of this study was nearly identical to the one conducted by this laboratory in 2005 (see above), but there was no stratification of subjects by BIA. The subjects were 10 HIV-positive patients who were maintained on two antiretroviral medications and had a history of smoking marijuana at least twice weekly for 4 weeks prior to entry into the study. On average, individuals had smoked 3 marijuana cigarettes per day, 5 times per week for 19 years.

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[34] Lean muscle mass was assessed using bioelectrical impedance analysis (BIA). The low-BIA group was classified with having <90% BIA, and the normal-BIA group was classified with having >90% BIA.

Subjects participated in 8 sessions that tested the acute effects of 0, 5 and 10 mg dronabinol oral capsules and marijuana cigarettes with 0, 2.0% and 3.9% THC concentration by weight, using a double-dummy design (with 4 sessions involving only one active drug and 4 interspersed placebo sessions). Both drug and placebo sessions lasted for 4 days each, with active drug administration occurring 4 times per day (every 4 hours). Testing occurred in two 16-day inpatient stays. In the intervening outpatient period, subjects were allowed to smoke marijuana prior to re-entry to the study unit for the second inpatient stay.

Marijuana was administered using a standardized cued procedure: (1) "light the cigarette" (30 seconds), (2) "prepare" (5 seconds), (3) "inhale" (5 seconds), (4) "hold smoke in lungs" (10 seconds), and (5) "exhale." Each subject smoked three puffs in this manner, with a 40-second interval between each puff.

Caloric intake was used as a surrogate measure for weight gain, but subjects were also weighed throughout the study (a measure which was not collected in the 2005 study by this group). Subjects received a box containing a variety of food and beverage items and were told to record consumption of these items following that day's administration of the test drug. Subjective measures included 0–100 point VAS for drug effect, good effect, bad effect, take drug again, drug liking, hungry, full, nauseated, thirsty, desire to eat. Neurocognitive measures and vital signs were monitored. Sleep was assessed using both the Nightcap sleep monitoring system and selected VAS measures related to sleep.

Both 5 and 10 mg dronabinol ($p <$ 0.008) and 2.0% and 3.9% THC marijuana ($p < 0.01$) dose-dependently increased caloric intake compared with placebo. This increase was generally accomplished through increases in incidents of eating, rather than an increase in the calories consumed in each incident. Subjects also gained similar amounts of weight after the highest dose of each cannabinoid treatment: 1.2 kg (2.6 lbs) after 4 days of 10 mg dronabinol, and 1.1 kg (2.4 lbs) after 4 days of 3.9% THC marijuana. The 3.9% THC marijuana dose also increased the desire to eat and ratings of hunger.

Ratings of good drug effect, high, drug liking, and desire to smoke again were significantly increased by 10 mg dronabinol and 2.0% and 3.9% THC marijuana doses compared to placebo. Both marijuana doses increased ratings of stimulated, friendly, and self-confident. The 10 mg dose of dronabinol increased ratings of concentration impairment, and the 2.0% THC marijuana dose increased ratings of anxious. Dry mouth was induced by 10 mg dronabinol (10 mg) and 2.0% THC marijuana. There were no changes in neurocognitive performance or objective sleep measures from administration of either cannabinoid. However, 3.9% THC marijuana increased subjective ratings of sleep.

The authors conclude that both dronabinol and smoked marijuana increase caloric intake and produce weight gain in HIV-positive patients. However, it is possible that the low degree of cognitive impairment reported in this study may reflect the development of tolerance to cannabinoids in this subject population, since all individuals had current histories of chronic marijuana use. This study produced positive results suggesting that marijuana should be studied further as a treatment for appetite stimulation in HIV patients.

3.3 Spasticity in Multiple Sclerosis

Only one randomized, double-blind, placebo-controlled Phase 2 study examined the effects of smoked marijuana on spasticity in MS.

This study was conducted by Corey-Bloom et al. (2012) and is entitled, "Smoked cannabis for spasticity in multiple sclerosis: A randomized, placebo-controlled trial". The subjects were 30 patients with MS-associated spasticity and had moderate increase in tone (score ≥ 3 points on the modified Ashworth scale). Participants were allowed to continue other MS medications, with the exception of benzodiazepines. Eighty percent of subjects had a history of marijuana use and 33% had used marijuana within the previous year.

Subjects participated in two 3-day test sessions, with an 11 day washout period. During each test session they smoked a 4.0% THC marijuana cigarette once per day or a placebo cigarette once per day. Smoking occurred through a standardized cued-puff procedure: (1) Inhalation for 5 seconds, (2) breath-hold and exhalation for 10 seconds, (3) pause between puffs for 45 seconds. Subjects completed an average of four puffs per cigarette.

The primary outcome measure was change in spasticity on the modified Ashworth scale. Additionally, subjects were assessed using a VAS for pain, a timed walk, and cognitive tests (Paced Auditory Serial Addition Test) and AEs.

Treatment with 4.0% THC marijuana reduced subject scores on the modified Ashworth scale by an average of 2.74 points more than placebo ($p < 0.0001$) and reduced VAS pain scores compared to placebo ($p = 0.008$). Scores on the cognitive measure decreased by 8.7 points more than placebo ($p = 0.003$). However, marijuana did not affect scores for the timed walk compared to placebo. Marijuana increased rating of feeling high compared to placebo.

7 subjects did not complete the study due to adverse events (two subjects felt uncomfortably "high", two had dizziness and one had fatigue). Of those 7 subjects who withdrew, 5 had little or no previous experience with marijuana. When the data were re-analyzed to include these drop-out subjects, with the presumption they did not have a positive response to treatment, the effect of marijuana was still significant on spasticity.

The authors conclude that smoked marijuana had usefulness in reducing pain and spasticity associated with MS. It is concerning that marijuana-naïve subjects dropped out of the study because they were unable to tolerate the psychiatric AEs induced by marijuana. The authors suggest that future studies should examine whether different doses can result in similar beneficial effects with less cognitive impact. However, the current study produced positive results suggesting that marijuana should be studied further as an adjunct treatment for spasticity in MS patients.

3.4 Asthma

Tashkin et al. (1974) examined bronchodilation in 10 subjects with bronchial asthma in the study entitled, "Acute Effects of Smoked Marijuana and Oral Δ^9-Tetrahydrocannabinol on Specific Airway Conductance in Asthmatic Subjects". The study was a double-blind, placebo-controlled, crossover design. All subjects were clinically stable at the time of the study; four subjects were symptom free, and six subjects had chronic symptoms of mild to moderate severity. Subjects were tested with 0.25ml of isoproterenol HCl prior to the study to ensure they responded to bronchodilator medications. Subjects were not allowed to take bronchodilator medication within 8 hours prior to the study. Previous experience with marijuana was not required for participation in the study, but 7 of the 10 subjects reported previous use of marijuana at a rate of less than 1 marijuana cigarette per month. No subjects reported marijuana use within 7 days of the study.

The study consisted of four test sessions with an interval of at least 48 hours between sessions. On two test sessions subjects smoked 7 mg/kg of body weight of either marijuana, with 2% THC concentration by weight, or placebo marijuana. During the other two test sessions, subjects ingested capsules with either 15mg of synthetic THC or placebo. Marijuana was administered using a uniform smoking technique: subjects inhaled deeply for 2–4 seconds, held smoke in lungs for 15 seconds, and resumed normal breathing for approximately 5 seconds. The author did not provide a description of the number of puffs taken at any smoking session. The authors state that the smoking procedure was repeated until the cigarette was consumed, which took approximately 10 minutes.

The outcome measure used was specific airway conductance (SGaw), as calculated using measurements of thoracic gas volume (TGV) and airway resistance (Raw) using a variable-pressure body plethysmograph. Additionally, an assessment of degree of intoxication was administered only to those subjects reporting previous marijuana use. This assessment consisted of subjects rating "how 'high' they felt" on a scale of 0–7, 7 representing "the 'highest' they had ever felt after smoking marijuana".

Marijuana produced a significant increase of 33–48% in average SGaw compared to both baseline and placebo ($P < 0.05$). This significant increase in SGaw lasted for at least 2 hours after administration. The average TGV significantly decreased by 4–13% compared to baseline and placebo ($P < 0.05$). The author stated that all subjects reported feelings of intoxication after marijuana administration.

The authors conclude that marijuana produced bronchodilation in clinically stable asthmatic subjects with minimal to moderate bronchospasms. Study limitations include: inclusion of subjects with varying severity of asthmatic symptoms, use of SGaw to measure lung responses to marijuana administration, and administration of smoke to asthmatic subjects. Smoke delivers a number of harmful substances and is not an optimal delivery symptom, especially for asthmatic patients. FEV1 via spirometry is the gold standard to assess changes in lung function, pre and post asthma treatment, by pharmacotherapy. SGaw has been shown to be a valid tool in bronchoconstriction lung assessment; however, since the FEV1 method was not utilized, it is unclear whether these results would correlate if the FEV1 method had been employed.

3.5 Glaucoma

Two randomized, double-blind, placebo-controlled Phase 2 clinical studies examined smoked marijuana in glaucoma (Crawford and Merritt, 1979; Merritt et al., 1980). In both studies, intraocular pressure (IOP) was significantly reduced 30 minutes after smoking marijuana. Maximal effects occurred 60–90 minutes after smoking, with IOP returning to baseline within 3–4 hours. These two studies were included in the 1999 IOM report on the medical uses of marijuana. Because our independent analysis of these studies concurred with the conclusions from the 1999 IOM report, these studies will not be discussed in further detail in this review. No recent studies have been conducted examining the effect of inhaled marijuana on IOP in glaucoma patients. This lack of recent studies may be attributed to the conclusions made in the 1999 IOM report that while cannabinoids can reduce intraocular pressure (IOP), the therapeutic effects require high doses that produce short-lasting responses, with a high degree of AEs. This high degree of AEs means that the potential harmful effects of chronic marijuana smoking may outweigh its modest benefits in the treatment of glaucoma.

3.6 Conclusions

Of the eleven randomized, double-blind, placebo-controlled Phase 2 clinical studies that met the criteria for review (see Sections 2.2 and 2.3), ten studies administered marijuana through smoking, while one study utilized marijuana vaporization. In these eleven studies, there were five different therapeutic indications: Five examined chronic neuropathic pain, two examined appetite stimulation in HIV patients, two examined glaucoma, one examined spasticity in MS, and one examined asthma.

There are limited conclusions that can be drawn from the data in these published studies evaluating marijuana for the treatment of different therapeutic indications. The analysis relied on published studies, thus information available about protocols, procedures, and results were limited to documents published and widely available in the public domain. The published studies on medical marijuana are effectively proof-of-concept studies. Proof-of-concept studies provide preliminary evidence on a proposed hypothesis regarding a drug's effect. For drugs under development, the effect often relates to a short-term clinical outcome being investigated. Proof-of-concept studies serve as the link between preclinical studies and dose ranging clinical studies. Therefore, proof-of-concept studies are not sufficient to demonstrate efficacy of a drug because they provide only preliminary information about the effects of a drug. Although these studies do not provide evidence that marijuana is effective in treating a specific, recognized disorder, these studies do support future larger well-controlled studies to assess the safety and efficacy of marijuana for a specific medical indication. Overall, the conclusions below are preliminary, based on very limited evidence.

3.6.1 Conclusions for Chronic Neuropathic Pain

In subjects with chronic neuropathic pain who are refractory to other pain treatments, five proof-of-concept studies produced positive results regarding the use of smoked marijuana for analgesia. However, the subjects in these studies continued to use their current analgesic drug regime, and thus no conclusions can be made regarding the potential efficacy of marijuana for neuropathic pain in patients not taking other analgesic drugs. Subjects also had numerous forms of neuropathic pain, making it difficult to identify whether a specific set of symptoms might be more responsive to the effects of marijuana. It is especially concerning that some marijuana-naïve subjects had intolerable psychiatric responses to marijuana exposure at analgesic doses.

3.6.2 Conclusions for Appetite Stimulation in HIV

In subjects who were HIV-positive, two proof-of-concept studies produced positive results with the use of both dronabinol and smoked marijuana to increase caloric intake and produce weight gain in HIV-positive patients. However, the amount of THC in the marijuana tested in these studies is four times greater than the dose of dronabinol typically tested for appetite stimulation (10 mg vs. 2.5 mg; Haney et al., 2005). Thus, it is possible that the low degree of AEs reported in this study may reflect the development of tolerance to cannabinoids in this patient population, since all individuals had current histories of chronic marijuana use. Thus, individuals with little prior exposure to marijuana may not respond similarly and may not be able to tolerate sufficient marijuana to produce appetite stimulation.

3.6.3 Conclusions for Spasticity in MS

In subjects with MS, a proof of concept study produced positive results using smoked marijuana as a treatment for pain and symptoms associated with treatment-resistant spasticity. The subjects in this study continued to take their current medication regiment, and thus no conclusions can be made regarding the potential efficacy of marijuana when taken on its own. It is also concerning that marijuana-naïve subjects dropped out of the study because they were unable to tolerate the psychiatric AEs induced by marijuana. The authors suggest that future studies should examine whether different doses can result in similar beneficial effects with less cognitive impact.

3.6.4 Conclusions for Asthma

In subjects with clinically stable asthma, a proof of concept study produced positive results of smoked marijuana producing bronchodilation. However, in this study marijuana was administered at rest and not while experiencing bronchospasms. Additionally, the administration of marijuana through smoking introduces harmful and irritating substances to the subject, which is undesirable especially in asthmatic patients. Thus the results suggest marijuana may have bronchodilator effects, but it may also have undesirable adverse effects in subjects with asthma.

3.6.5 Conclusions for Glaucoma

As noted in Sections 3.5, the two studies that evaluated smoked marijuana for glaucoma were conducted decades ago, and they have been thoroughly evaluated in the 1999 IOM report. The 1999 IOM report concludes that while the studies with marijuana showed positive results for reduction in IOP, the effect is short-lasting, requires a high dose, and is associated with many AEs. Thus, the potential harmful effects may outweigh any modest benefit of marijuana for this condition. We agree with the conclusions drawn in the 1999 IOM report.

3.7 Design Challenges for Future Studies

The positive results reported by the studies discussed in this review support the conduct of more rigorous studies in the future. This section discusses methodological challenges that have occurred in clinical studies with smoked marijuana. These design issues should be addressed when larger-scale clinical studies are conducted to ensure that valid scientific data are generated in studies evaluating marijuana's safety and efficacy for a particular therapeutic use.

3.7.1 Sample Size

The ability for results from a clinical study to be generalized to a broader population is reliant on having a sufficiently large study sample size. However, as noted above, all of the 11 studies reviewed in this document were early Phase 2 proof of concept studies for efficacy and safety. Thus, the sample sizes used in these studies were inherently small, ranging from 10 subjects per treatment group (Tashkin et al., 1974; Haney et al., 2007) to 25 subjects per treatment group (Abrams et al., 2007). These sample sizes are statistically inadequate to support a showing of safety or efficacy. FDA's recommendations about sample sizes for clinical trials can be found in the *Guidance for Industry: E9 Statistical Principles for Clinical Trials (1998).*[35] For example, "the number of subjects in a clinical trial should always be large enough to provide a reliable answer to the questions addressed. This number is usually determined by the primary objective of the trial. The method by which the sample size is calculated should be given in the protocol, together with the estimates of any quantities used in the calculations (such as variances, mean values, response rates, event rates, difference to be detected)." (pg. 21). Other clinical FDA *Guidance for Industry*[36] may also contain recommendations regarding the appropriate number of subjects that should be investigated for a specific medical indication.

3.7.2 Marijuana Dose Standardization

Dose standardization is critical for any clinical study in order to ensure that each subject receives a consistent exposure to the test drug. The *Guidance for Industry: Botanical Drug Products* (2004)[37] provides specific information on the development of botanical drug products. Specifically, this guidance includes information about the need for well-characterized and consistent chemistry for the botanical plant product and for consistent and reliable dosing. Specifically for marijuana studies, dose standardization is important because if marijuana leads to plasma levels of cannabinoids that are significantly different between subjects, this variation may lead to differences in therapeutic responsivity or in the prevalence of psychiatric AEs.

In most marijuana studies discussed in this review, investigators use a standardized cued smoking procedure. In this procedure, a subject is instructed to inhale marijuana smoke for 5 seconds, hold the smoke in the lungs for 10 seconds, exhale and breathe normally for 40 seconds. This process is repeated to obtain the desired dose of the drug. However, this procedure may not lead to equivalent exposure to marijuana and its constituent cannabinoids, based on several factors:

- Intentional or unintentional differences in the depth of inhalation may change the amount of smoke in the subject's lungs.
- Smoking results in loss from side stream smoke, such that the entire dose is not delivered to the subject.
- There may be differences in THC concentration along the length of a marijuana cigarette. According to Tashkin et al. (1991), the area of the cigarette closest to the mouth tends to accumulate a higher concentration of THC, but this section of the cigarette is not smoked during a study.

For example, Wilsey et al. (2008) used this standardized smoking procedure. The reported mean (range) of marijuana cigarettes consumed was 550 mg (200–830mg) for the low strength marijuana (3.5% THC) and 490 mg (270–870mg) for the high strength marijuana (7% THC). This wide range of amounts of marijuana cigarette smoked by the individual subjects, even with standardized smoking procedure and controlled number of puffs, supports the issues with delivering consistent doses with smoke marijuana.

In other marijuana studies that do not use a cued smoking procedure, subjects are simply told to smoke the marijuana cigarette over a specific amount of time (usually 10 minutes) without further instruction (Crawford and Merritt, 1979; Merritt et al., 1980; Ellis et al., 2009). The use of a nonstandardized procedure may lead to non-equivalent exposures to marijuana and its constituent cannabinoids between subjects because of additional factors that are not listed above, such as:

- Differences in absorption and drug response if subjects (especially marijuana-naïve ones) are not instructed to hold marijuana smoke in their lungs for a certain period of time.

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[35] The *Guidance for Industry: E9 Statistical Principles for Clinical Trials* can be found at: *www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073137.pdf.*

[36] Other Guidances for Industry can be found at: *www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm064981.htm.*

[37] The *Guidance for Industry: Botanical Drug Products* can be found at: *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070491.pdf.*

- Prolonged periods between puffs may increase loss to side stream smoke.
- Subjects may attempt to smoke the marijuana cigarette in the way they would smoke a tobacco cigarette, which relies primarily on short, shallow puffs.

In both standardized and non-standardized smoking procedures, subjects may seek to control the dose of THC through self-titration (Crawford and Merritt, 1979; Merritt et al., 1980; Tashkin et al., 1974; Abrams et al., 2007; Ellis et al., 2009). Self-titration involves an individual moderating the amount of marijuana smoke inhaled over time in order to obtain a preferred level of psychoactive or clinical response. The ability of an individual to self-titrate by smoking is one reason given by advocates of "medical marijuana" in support of smoking of marijuana rather than through its ingestion via edibles. However, for research purposes, self-titration interferes with the ability to maintain consistent dosing levels between subjects, and thus, valid comparisons between study groups.

All of these factors can make the exact dose of cannabinoids received by a subject in a marijuana study difficult to determine with accuracy. Testing whether plasma levels of THC or other cannabinoids are similar between subjects following the smoking procedure would establish whether the procedure is producing appropriate results. Additionally, studies could be conducted to determine if vaporization can be used to deliver consistent doses of cannabinoids from marijuana plant material. Specifically, vaporization devices that involve the collection of vapors in an enclosed bag or chamber may help with delivery of consistent doses of marijuana. Thus, more information could be collected on whether vaporization is comparable to or different than smoking in terms of producing similar plasma levels of THC in subjects using identical marijuana plant material.

3.7.3 Acute vs. Chronic Therapeutic Marijuana Use

The studies that were reviewed administered the drug for short durations lasting no longer than 5 days (Abrams et al., 2007; Ellis et al., 2009; Ware et al., 2010). Thus all studies examined the short-term effect of marijuana administration for therapeutic purposes. However, many of the medical conditions that have been studied are persistent or expected to last the rest of a patient's life. Therefore, data on chronic exposure to smoked marijuana in clinical studies is needed. In this way, more information will be available regarding whether tolerance, physical dependence, or specific adverse events develop over the course of time with continuing use of therapeutic marijuana.

3.7.4 Smoking as a Route of Administration

As has been pointed out by the IOM and other groups, smoking is not an optimum route of administration for marijuana-derived therapeutic drug products, primarily because introducing the smoke from a burnt botanical substance into the lungs of individuals with a disease state is not recommended when their bodies may be physically compromised. The 1999 IOM report on medicinal uses of marijuana noted that alternative delivery methods offering the same ability of dose titration as smoking marijuana will be beneficial and may limit some of the possible long-term health consequences of smoking marijuana. The primary alternative to smoked marijuana is vaporization, which can reduce exposure to combusted plant material containing cannabinoids. The only study to use vaporization as the delivery method was Wilsey et al. (2013). The results from Wilsey et al. (2013) showed a similar effect of decreased pain as seen in the other studies using smoking as the delivery method (Ware et al., 2010; Wilsey et al., 2008). This similar effect of decrease pain supports vaporization as a possibly viable route to administer marijuana in research, while potentially limiting the risks associated with smoking.

3.7.5 Difficulty in Blinding of Drug Conditions

An adequate and well-controlled clinical study involves double-blinding, where both the subjects and the investigators are unable to tell the difference between the test treatments (typically consisting of at least a test drug and placebo) when they are administered. All of the studies reviewed in this document administered study treatments under double-blind conditions and thus were considered to have an appropriate study design.

However, even under the most rigorous experimental conditions, blinding can be difficult in studies with smoked marijuana because the rapid onset of psychoactive effects readily distinguishes active from placebo marijuana. The presence of psychoactive effects also occurs with other drugs. However, most other drugs have a similar psychoactive effect with substances with similar mechanisms of actions. These substances can be used as positive controls to help maintain blinding to the active drug being tested. Marijuana on the other hand, has a unique set of psychoactive effects which makes the use of appropriate positive controls difficult (Barrett et al., 1995). However, two studies did use Dronabinol as a positive control drug to help maintain blinding (Haney et al., 2005; Haney et al., 2007).

When blinding is done using only placebo marijuana, the ability to distinguish active from placebo marijuana may lead to expectation bias and an alteration in perceived responsivity to the therapeutic outcome measures. With marijuana-experienced subjects, for example, there may be an early recognition of the more subtle cannabinoid effects that can serve as a harbinger of stronger effects, which is less likely to occur with marijuana-naïve subjects. To reduce this possibility, investigators have tested doses of marijuana other than the one they were interested in experimentally to maintain the blind (Ware et al., 2010).

Blinding can also be compromised by differences in the appearance of marijuana plant material based on THC concentration. Marijuana with higher concentrations of THC tends to be heavier and seemingly darker, with more "tar-like" substance. Subjects who have experience with marijuana have reported being able to identify marijuana from placebo cigarettes by sight alone when the plant material in a cigarette was visible (Tashkin et al., 1974; Ware et al., 2010). Thus, to maintain a double-blind design, many studies obscure the appearance of plant material by closing both ends of the marijuana cigarette and placing it in in an opaque plastic tube.

While none of these methods to secure blinding may be completely effective, it is important to reduce bias as much as possible to produce consistent results between subjects under the same experimental conditions.

3.7.6 Prior Marijuana Experience

Marijuana use histories in test subjects may influence outcomes, related to both therapeutic responsivity and psychiatric AEs. Marijuana-naïve subjects may also experience a marijuana drug product as so aversive that they would not want to use the drug product. Thus, subjects' prior experience with marijuana may affect the conduct and results of studies.

Most of the studies reviewed in this document required that subjects have a history of marijuana use (see tables in Appendix that describe specific requirements for each study). However, in studies published in the scientific literature, the full inclusion criteria with regard to specific amount of experience with marijuana may not be provided. For those studies that do provide inclusion criteria, acceptable experience with marijuana can range from once in a lifetime to use multiple times a day.

The varying histories of use might affect everything from scores on adverse event measures, safety measures, or efficacy measures. Additionally, varying amounts of experience can impact cognitive effect measures assessed during acute administration studies. For instance, Schreiner and Dunn (2012) contend cognitive deficits in heavy marijuana users continue for approximately 28 days after cessation of smoking. Studies requiring less than a month of abstinence prior to the study may still see residual effects of heavy use at baseline and after placebo marijuana administration, thus showing no significant effects on cognitive measures. However, these same measurements in occasional or naïve marijuana users may demonstrate a significant effect after acute marijuana administration. Therefore, the amount of experience and the duration of abstinence of marijuana use are important to keep in mind when analyzing results for cognitive and other adverse event measures. Lastly, a study population with previous experience with marijuana may underreport the incidence and severity of adverse events. Because most studies used subjects with prior marijuana experience, we are limited in our ability to generalize the results, especially for safety measures, to marijuana naïve populations.

Five of 11 studies reviewed in this document included both marijuana-naïve and marijuana-experienced subjects (Corey-Bloom et al., 2012; Ellis et al., 2009; Ware et al., 2010; Merritt et al., 1980; Tashkin et al., 1974). Since the number of marijuana-naïve subjects in these studies was low, it was not possible to conduct a separate analysis compared to experienced users. However, systematically evaluating the effect of marijuana experience on study outcomes is important, since many patients who might use a marijuana product for a therapeutic use will be marijuana-naïve.

Research shows that marijuana-experienced subjects have a higher ability to tolerate stronger doses of oral dronabinol than marijuana-naïve subjects (Haney et al., 2005). Possibly, this increased tolerance is also the case when subjects smoke or vaporize marijuana. Thus, studies could be conducted that investigate the role of marijuana experience in determining tolerability of and responses to a variety of THC concentrations in marijuana.

3.7.7 Inclusion and Exclusion Criteria

For safety reasons, all clinical studies have inclusion and exclusion criteria that restrict the participation of individuals with certain medical conditions. For studies that test marijuana, these criteria may be based on risks associated with exposure to smoked material and the effects of THC. Thus, most studies investigating marijuana require that subjects qualify for the study based on restrictive symptom criteria such that individuals do not have other symptoms that may be known to interact poorly with cannabinoids.

Similarly, clinical studies with marijuana typically exclude individuals with cardiac or pulmonary problems, as well as psychiatric disorders. These exclusion criteria are based on the well-known effects of marijuana smoke to produce increases in heart rate and blood pressure, lung irritation, and the exacerbation of psychiatric disturbances in vulnerable individuals. Although these criteria are medically reasonable for research protocols, it is likely that future marijuana products will be used in patients who have cardiac, pulmonary or psychiatric conditions. Thus, individuals with these conditions should be evaluated, whenever possible.

Additionally, all studies reviewed in this document allowed the subjects to continue taking their current regimen of medications. Thus all results evaluated marijuana as an adjunct treatment for each therapeutic indication.

3.7.8 Number of Female Subjects

A common problem in clinical research is the limited number of females who participate in the studies. This problem is present in the 11 studies reviewed in this document, in which one study did not include any female subjects (Ellis et al., 2009), and three studies had a low percentage of female subjects (Abrams et al., 2007; Haney et al., 2005; Haney et al., 2007). However, each of these four studies investigated an HIV-positive patient population, where there may have been a larger male population pool from which to recruit compared to females.

Since there is some evidence that the density of CB1 receptors in the brain may vary between males and females (Crane et al., 2012), there may be differing therapeutic or subjective responsivity to marijuana. Studies using a study population that is equal parts male and female may show whether and how the effects of marijuana differ between male and female subjects.

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Appendix (Tables)

Table 1: Randomized, controlled, double-blind trials examining smoked marijuana in treatment of neuropathic pain

Author & Date *Indication*	**Subjects (n) completed/randomized Subject characteristics**	**Drugs Admin. Methods**	**Study Type** *Duration*	**Primary Outcome Measure**	**Primary Outcome Measure Results**	**Adverse events/AEs**
Abrams et al. (2007) *HIV-Sensory Neuropathy; Neuropathic Pain*	Marijuana Group: 25/27 22 males 5 females Placebo Group: 25/28 26 males 2 females Inclusion Criteria: -documented HIV -documented HIV-SN -pain score ≥30mm VAS -prior marijuana use of six or more times in lifetime Previous Marijuana Experience: -marijuana group: 21 current users -placebo group: 19 current users Exclusion Criteria: -substance abuse (including tobacco) -family history of neuropathy due to causes not HIV related -use of isoniazid, dapsone, or metronidazole within 8 weeks of enrollment	NIDA marijuana, smoked 0%, 3.65% THC Smoking Procedure: -signal light cued smoking of marijuana cigarette with each puff consisting of: 1) 5s inhale smoke, 2) 10s hold smoke in lungs 3) 40s exhale and breath normally 4) repeat procedure for desired number of puffs # of puffs not specified, only specified that subjects smoked the entire marijuana/placebo cigarette On 1st and last day of intervention period BID. For all other days TID	Parallel Group *5-day treatment period*	VAS daily pain score	-52% of the marijuana group showed >30% decrease in pain score compared to 24% of placebo group. -Marijuana group had significantly greater reduction in daily pain score than placebo group. -NNT=3.6	-Rating for adverse events of anxiety, sedation, disorientation, confusion, and dizziness were significantly higher in the marijuana group compared to placebo group. -Marijuana and placebo groups showed a reduction in total mood disturbance on POMS. AEs: -1 grade 3 dizziness in marijuana group -2 grade 3 anxiety, 1 in each group.
Ellis et al. (2009) *HIV Sensory Neuropathy; Neuropathic*	28/34 28 males Inclusion Criteria: -documented HIV -documented neuropathic	NIDA marijuana, smoked 0%, 1%, 2%, 4%, 6%, 8% THC Smoking Procedures:	Crossover Dose-titration (on 1st day)	Pain magnitude on DDS	-Pain reduction was significantly greater after marijuana compared to placebo.	-Mood disturbance, quality of life, and psychical disability improved for both marijuana and placebo. -Moderate to severe adverse events were more common with marijuana than placebo.

Author & Date *Indication*	Subjects (n) completed/randomized Subject characteristics	Drugs Admin. Methods	Study Type *Duration*	Primary Outcome Measure	Primary Outcome Measure Results	Adverse events/AEs
Pain	pain refractory to ≥2 analgesics -pain score ≥5 on pain intensity subscale of DDS Previous Marijuana Experience: -27 subjects had previous experience -63% of subjects had no exposure for >1 year before study Exclusion Criteria: -current DSM-IV substance abuse disorder -lifetime history of dependence on marijuana -previous psychosis with or intolerance to cannabinoids -concurrent use of approved cannabinoid medications -positive UDS for cannabinoids during wash-in week -serious medical conditions that affect safety -alcohol or drug dependence within 12 months of study	- Verbally cued smoking of marijuana cigarette with each puff consisting of: 1) 5s inhale smoke, 2) 10s hold smoke in lungs 3) 40s exhale and breath normally 4) repeat procedure for desired number of puffs -unknown number of puffs QID	*2, 5-day treatment phase, with 2-week washout period*		-NNT=3.5	-HIV disease parameters did not differ for marijuana or placebo. -Adverse events included: concentration difficulties, fatigue, sleepiness or sedation, increased duration of sleep, reduced salivation, and thirst. These adverse events were more frequent in marijuana compared to placebo. Withdrawals for drug related reasons: -1 cannabis-naïve subject had acute cannabis-induced psychosis -1 subjects developed an intractable smoking-related cough during marijuana administration
Wilsey et al. (2008) *Neuropathic pain; Various Causes*	32/38 20 males 18 females Inclusion Criteria: -CRPS type I, spinal cord	NIDA marijuana, smoked 0%, 3.55%, 7% THC Smoking Procedure: Verbally cued	Crossover *3, 6-hour sessions, with 3-day between*	VAS spontaneous pain intensity	-A significant decrease in pain intensity for both strengths of marijuana compared to placebo	-7% THC marijuana significantly decreased functioning on neurocognitive measures compared to placebo. -Subjective effects were greater for 7% THC marijuana than 3.55%

Author & Date *Indication*	**Subjects (n) completed/randomized Subject characteristics**	**Drugs Admin. Methods**	**Study Type** ***Duration***	**Primary Outcome Measure**	**Primary Outcome Measure Results**	**Adverse events/AEs**
	injury, peripheral neuropathy, or nerve damage -previous marijuana use Previous Marijuana Experience: -median (range) time from previous exposure: 1.7 years (31 days to 30 years) -median (range) exposure duration: 2 years (1 day to 22 years). Exclusion Criteria: -no marijuana or cannabinoid medication use for 30 days prior to study; confirmed by UDS -severe depression -history of schizophrenia or bipolar depression -uncontrolled hypertension, cardiovascular disease, and pulmonary disease -active substance abuse	smoking of marijuana cigarette with each puff consisting of: 1) 5s inhale smoke, 2) 10s hold smoke in lungs 3) 40s exhale and breath normally 4) repeat procedure for desired number of puffs Cumulative dosing procedure: -escalate the number of puffs from 2 to 4 puffs over 3 smoking sessions with 1 hour between sessions TID	*sessions*			THC marijuana with significantly more ratings of good drug effect, bad drug effect, feeling high, feeling stoned, impaired, sedation, confusion, and hunger compared to placebo.
Ware et al. (2010) *Post-traumatic or postsurgical neuropathic pain*	21/23 11 males 12 females Inclusion Criteria: -neuropathic pain for ≥ 3 months caused by trauma or surgery -allodynia and hyperalgesia -pain score >4cm VAS -no marijuana use for 1	NIDA placebo; Prairie Plant System Inc. (Canada) marijuana, smoked 0%, 2.5%, 6%, 9.4% THC (25 mg of marijuana/placebo plant material was placed in opaque	Crossover *4, 5-day out-patient* treatment phase, with 9-day washout periods*	Pain intensity on 11-item NRS	-Average daily pain intensity was significantly lower after 9.4% THC compared to placebo.	-Anxiety and depression were significantly improved with 9.4% THC compared to placebo. -No significant difference between placebo and 9.4% THC for subjective effects. AEs: -248 mild AEs were reported -6 moderate AEs were reported: 2 fall, 1 increased pain, 1 numbness,

Author & Date *Indication*	Subjects (n) completed/randomized Subject characteristics	Drugs Admin. Methods	Study Type *Duration*	Primary Outcome Measure	Primary Outcome Measure Results	Adverse events/AEs
	year prior to study -stable analgesic regimen -normal liver and renal function Previous Marijuana Experience: -18 subjects had used marijuana before Exclusion Criteria: -pain due to cancer or nociceptive causes -significant cardiac or pulmonary disease -current substance abuse or dependence (including marijuana) -history of psychotic disorders -current suicidal ideations	gelatin capsules) Smoking Procedures: -1) Break one capsule open and tip content into the bowl of a titanium pipe 2) light marijuana material 3) 5s inhale smoke 4) 10s hold smoke in lungs 5) Exhale 1 puff burned all 25 mg of plant material TID Intermediate doses were used to help maintain blinding				1 drowsiness, 1 pneumonia -Most frequently reported drug-related AEs for 9.4% THC: headache, dry eyes, burning sensation, dizziness, numbness, and cough. Withdrawals for drug related reason: -1 subject had increased pain after 6% THC administration -1 subject tested positive for cannabinoids in urine test during placebo treatment
Wilsey et al. (2013) *Neuropathic Pain; Various Causes*	36/39 28 males 11 females Inclusion Criteria: -CRPS type 1, thalamic pain, spinal cord injury, peripheral neuropathy, radiculopathy, or nerve injury -previous marijuana use Previous Marijuana Experience: - median (range) time from last exposure prior to	NIDA marijuana, vaporized 0%, 1.29%, 3.53% THC Smoking Procedures: - Verbally cued inhalation of vaporized material in the balloon with each puff consisting of: 1) 5s inhale vapors, 2) 10s hold vapors in lungs 3) 40s exhale and breath normally	Crossover *3, 6-hour sessions, with at least 3 days between sessions*	VAS spontaneous pain intensity	-Number of subjects that showed a 30% reduction in pain intensity was significantly greater for both strengths of marijuana compared to placebo. -Both strengths of marijuana showed a similar significant decrease in pain compared to placebo. -NNT=3.2 for 1.29% THC marijuana vs.	-Scores for feeling stoned, feeling high, like the drug effect, feeling sedated, and feeling confused were significantly greater for 3.53% THC marijuana compared to 1.29% THC marijuana, and for both strengths of marijuana compared to placebo. -Scores for feeling drunk and feeling impaired are significantly greater in both strengths of marijuana compared to placebo. -Scores for desired more of the drug were significantly greater for 1.29% THC marijuana compared to placebo, with no significant

Author & Date *Indication*	**Subjects (n) completed/randomized Subject characteristics**	**Drugs Admin. Methods**	**Study Type** ***Duration***	**Primary Outcome Measure**	**Primary Outcome Measure Results**	**Adverse events/AEs**
	screening: 9.6 years (1 day to 45 years) -16 current marijuana users and 23 past users -# smoked daily: 6 current users, 5 past users -# used approx. once every 2 weeks: 8 current users, 6 past users -# used once every 4 weeks or less: 2 current users, 12 past users Exclusion Criteria: -no marijuana or cannabinoid medication use for 30 days prior to study; confirmed by UDS -severe depression -suicidal ideations -diagnoses of serious mental illness -uncontrolled hypertension, cardiovascular disease, or chronic pulmonary disease -active substance abuse	4) repeat procedure for desired number of puffs BID Cumulative & Flexible Dosing: -1st drug admin. consisted of 4 puffs from balloon. -Followed 2 hours later by 2nd drug admin. -2nd drug admin. consisted of 4 to 8 puffs from balloon; number of puffs taken was left up to the subject so they could self-titrate to their target does, which balanced desired response and tolerance levels.			placebo. -NNT=2.9 for 3.53% THC marijuana vs. placebo.	difference seen for 3.53% THC marijuana. -3.53% THC marijuana had significantly worse performance than 1.29% THC marijuana for learning and memory. -Both strengths of marijuana significantly reduced scores on attention compared to placebo.

*Out-patient: subjects were given enough doses of marijuana/placebo to last the 5-day treatment phase, and then were sent home for the remainder of the treatment phase.
AE=Adverse Event; BID=drug administered two times per day; CRPS=complex regional pain syndrome; DDS=Descriptor Differential Scale; NIDA=National Institute of Drug Abuse; NNT=Number Needed to Treat; NRS=Numeric Rating Scale; QID=drug administered four times per day; THC=delta-9-tetrahydrocannbinol; TID=drug administered three times per day; UDS=urine drug screen; VAS=Visual Analog Scale.

Table 2: **Randomized, controlled, double-blind trials examining smoked marijuana in treatment of appetite stimulation in HIV/AIDS**

Author & Date ***Indication***	**Subjects (n) completed/randomized Subject characteristics**	**Drugs Admin. Methods**	**Study Type** ***Duration***	**Primary Outcome Measure**	**Results (summary)**	**Adverse events/AEs**
Haney et al. (2005) *HIV+ with either normal muscle mass (Normal-BIA) or clinically significant loss of muscle mass (Low-BIA)*	Low-BIA: 15/17 12 males 3 females Normal-BIA: 15/18 15 males Inclusion Criteria: -21-50 years of age -prescribed at least 2 antiretroviral medications -currently under the care of a physician for HIV management -medically and psychiatrically stable -smoke marijuana ≥ 2x/week for past 4 weeks Previous Marijuana Experience: -mean (SD) # of days/week of marijuana use: Low-BIA= 6 (2); Normal-BIA=5 (2) -mean (SD) # marijuana cigarettes/day: Low-BIA=3 (2); Normal-BIA=3 (1) -mean (SD) years of marijuana use: Low-BIA=12.2 (8.3); Normal-BIA=10.8 (2.6) Exclusion Criteria: -diagnosis of nutritional	NIDA marijuana, smoked 0%, 1.8%, 2.8%, 3.9% THC Dronabinol, oral 0, 10, 20, 30mg Double-dummy drug admin. Procedures: -only 1 active dose per session -one dronabinol/placebo capsule followed 1 hour later by marijuana/placebo smoking Smoking Procedures: Verbally cued smoking of marijuana cigarette with each puff consisting of: 1) 5s inhale smoke, 2) 10s hold smoke in lungs 3) 40s exhale and breath normally 4) repeat for 3 puffs per smoking session	Crossover *8, 7-hour session, with at least 1 day between sessions*	No primary outcome measure is specified Related outcome measure was caloric intake	-In Low-BIA all dronabinol doses and 1.8% and 3.9% THC marijuana significantly increased caloric intake compared with placebo.	-Ratings of high and good drug effect were significantly increased for all strengths of marijuana and all doses of dronabinol except 10mg dronabinol. -3.9% THC significantly increased ratings of dry mouth and thirsty compared to placebo. -Low-BIA group showed no significant adverse event ratings, and in the normal-BIA group the only significant adverse events in response to marijuana included: diarrhea after 3.9% THC marijuana. -Dronabinol had more incidences of adverse events at all doses compared to marijuana.

Author & Date *Indication*	**Subjects (n) completed/randomized Subject characteristics**	**Drugs Admin. Methods**	**Study Type** *Duration*	**Primary Outcome Measure**	**Results (summary)**	**Adverse events/AEs**
	malabsorption, major depression, dementia, chronic diarrhea, weakness, fever, significant pulmonary disease -an opportunistic infection within past 3 months -obesity -use of steroids within past 3 weeks -drug dependence (excluding marijuana or nicotine)	QD				
Haney et al. (2007) *HIV+*	10 9 males 1 female Inclusion Criteria: -21-50 years of age -taking ≥ 2 antiretroviral medications -under the care of a physician for HIV management -medically and psychiatrically stable -smoke marijuana ≥ 2x/week for the past 4 weeks Previous Marijuana Experience: -mean (SD) # of days/week of marijuana use: 4.6 (0.6)	NIDA marijuana, smoked 0%, 2%, 3.9% THC Dronabinol, oral 0, 5, 10mg Double-dummy drug admin. Procedures: -only 1 active dose per session -one dronabinol/placebo capsule followed 1 hour later by marijuana/placebo smoking Smoking Procedures:	Crossover *2, 16-day treatment phases, with 5-10 days between phases* *Each 16-day treatment phase consisted of 2, 4-day active drug period with 4-day placebo period between active drug periods.*	No primary outcome measure is specified Related outcome measures were Caloric Intake & Body Weight	-Both strengths of marijuana significantly increased caloric intake compared to placebo. -3.9% THC marijuana significantly increased body weight compared to placebo.	-Both strengths of marijuana significantly increased ratings of: good drug effect, high, mellow, stimulate, friendly, and self-confident. Only 2% THC marijuana significantly increased ratings of anxious. -Both strengths of marijuana significantly increased subjective measures for satisfied sleep and estimated time of sleep.

Author & Date *Indication*	**Subjects (n) completed/randomized Subject characteristics**	**Drugs Admin. Methods**	**Study Type** *Duration*	**Primary Outcome Measure**	**Results (summary)**	**Adverse events/AEs**
	-mean (SD) # marijuana cigarettes/day: 3.2 (0.8) -mean (SD) years of marijuana use: 18.6 (3.3) Exclusion Criteria: -diagnosis of nutritional malabsorption, major depression, dementia, chronic diarrhea, weakness, fever, significant pulmonary disease -an opportunistic infection within past 3 months -obesity -use of steroids within past 3 weeks -drug dependence (excluding marijuana or nicotine)	Light cued smoking of marijuana cigarette with each puff consisting of: 1) 5s inhale smoke, 2) 10s hold smoke in lungs 3) 40s exhale and breath normally 4) repeat for 3 puffs per smoking session QID				

AE=Adverse Event; BIA=Bioelectric Impedance Analysis; NIDA=National Institute of Drug Abuse; QD=drug administered one time per day; QID=drug administered four times per day; THC=delta-9-tetrahydrocannbinol

Table 3: Randomized, controlled, double-blind trails examining smoked marijuana in treatment of spasticity in Multiple Sclerosis

Author & Date ***Indication***	**Subjects (n) completed/randomized Subject characteristics**	**Drugs Admin. Methods**	**Study Type** ***Duration***	**Primary Outcome Measure**	**Primary Outcome Measure Results**	**Adverse events/AEs**
Corey-Bloom et al. (2012) *Multiple Sclerosis; Spasticity*	30/37 11 males 19 females Inclusion Criteria: -documented MS -spasticity -moderate increase in tone (score > 3 on modified Ashworth scale Previous Marijuana Experience: -24 subjects had previous exposure to marijuana -10 subjects used marijuana within the year Exclusion Criteria: -no marijuana smoking for ≤1 month prior to screening -psychiatric disorder (other than depression) -history of substance use -substantial neurological disease other than MS -severe or unstable medical illnesses -known pulmonary disorders -using high dose narcotic medication for pain -using benzodiazepines to control spasticity	NIDA marijuana, smoked 0%, 4% THC Smoking Procedure: smoking of marijuana cigarette with each puff consisting of: 1) 5s inhale smoke, 2) 10s hold smoke in lungs 3) 45s exhale and breath normally 4) repeat for an average of 4 puffs per smoking session QD	Crossover *2, 3-day treatment periods, with 11 day washout period*	Spasticity on the Modified Ashworth Scale	-Smoking marijuana significantly reduced spasticity scores compared to placebo	-Marijuana reduced scores on cognitive measure compared to placebo. -Marijuana significantly increased perceptions of "highness" compared to placebo Withdrawals for drug-related reasons: -2 subjects felt uncomfortably high -2 dizziness -1 fatigue

AE=Adverse Event; MS= Multiple Sclerosis; NIDA=National Institute of Drug Abuse; QD=drug administered one time per day; THC=delta-9-tetrahydrocannbinol

Table 4: Randomized, controlled, double-blind trails examining smoked marijuana in treatment of intraocular pressure in Glaucoma

Author & Date ***Indication***	**Subjects (n) completed/randomized Subject characteristics**	**Drugs Admin. Methods**	**Study Type** ***Duration***	**Primary Outcome Measure**	**Results (summary)**	**Adverse events/AEs**
Crawford & Merritt (1979) *Hypertensive and Normotensive Glaucoma*	HT group: 8 4 males 4 females NT group: 8 4 males 4 females Inclusion Criteria: -documented glaucoma Previous Marijuana Experience: -all were marijuana naïve Exclusion Criteria: -coronary artery disease	NIDA marijuana, smoked 0%, 2.8% THC Smoking Procedure: -instructed to inhale 20 times deeply and retain smoke in lungs -smoke marijuana/placebo cigarette in 5 minutes QD	Crossover *4, 1-day sessions, no time between sessions*	No primary outcome measure is specified Related outcome measure was IOP	-Marijuana decreased IOP by 37-44% from baseline. -The maximal decrease in IOP was significantly greater in HT (-14mmHg) than NT (-9mmHg) after marijuana .	-Placebo marijuana increased heart rate for 10 minutes in both groups. -The maximal increase in heart rate was significantly greater in NT than HT after marijuana. -The maximal decrease in blood pressure was significantly greater in HT than NT after marijuana.
Merritt et al. (1980) *Glaucoma*	18 12 males 6 females (31 glaucoma eyes, analyzed results for each eye) Inclusion Criteria: -documented glaucoma Previous Marijuana Experience: -9 subjects had used marijuana at least once Exclusion Criteria: -cardiac, neurological,	NIDA marijuana, smoked 0%, 2% THC Smoking Procedure: -None described -smoked 1 marijuana/placebo cigarette over 10-20 minutes QD	Crossover *2, 1-day sessions*	No primary outcome measure is specified Related outcome measure was IOP	-Marijuana significantly decreased IOP compared to placebo	-Marijuana significantly increased heart rate compared to placebo -Blood pressure significantly decreased after marijuana -All subjects experienced hunger, thirst, euphoria, drowsy, and feeling cold -Observed adverse events were greater in marijuana naïve subjects than in subjects with prior marijuana experience. AEs: -5 subjects postural hypotension -8 subjects anxiety with

Author & Date *Indication*	**Subjects (n) completed/randomized Subject characteristics**	**Drugs Admin. Methods**	**Study Type** *Duration*	**Primary Outcome Measure**	**Results (summary)**	**Adverse events/AEs**
	and psychiatric dysfunction					tachycardia and palpitations

AE=Adverse Event; HT=Hypertensive; IOP=Intraocular pressure; NIDA=National Institute of Drug Abuse; NT=Normotensive; QD=drug administered one time per day; THC=delta-9-tetrahydrocannbinol

Table 5: Randomized, controlled, double-blind trails examining smoked marijuana in treatment of asthma

Author & Date *Indication*	**Subjects (n) completed/randomized Subject characteristics**	**Drugs Admin. Methods**	**Study Design** *Duration*	**Primary Outcome Measure**	**Results (summary)**	**Adverse events/AEs**
Tashkin et al. (1974) *Bronchial Asthma*	10 5 males 5 females Inclusion Criteria: -diagnosis of bronchial asthma -asthma relieved by bronchodilator medication -clinically stable Previous Marijuana Experience: -7 subjects had previous exposure to marijuana -amount of exposure <1 cigarette/month Exclusion Criteria: -no marijuana use ≤7 days of study -psychiatric illness	NIMH (NIDA) marijuana, smoked 0%, 2% THC Dronabinol, oral 0, 15mg Dosing is 7mg/kg of body weight of plant material Smoking Procedure: smoking of marijuana cigarette with each puff consisting of: 1) 2-4s deep inhale smoke, 2) 15s hold smoke in lungs 3) 5s exhale and breath normally 4) repeat till entire cigarette is smoked QD	Crossover *4, 1-day sessions, with at least 48 hours between sessions*	No primary outcome measure is specified Related outcome measure was sGaw	-Marijuana significantly increased sGaw (33-48%) compared to placebo and baseline	-Marijuana initially significantly increased pulse rate compared to placebo, and then at 90 minutes pulse rate was significantly decreased compared to baseline. -All subjects felt intoxicated after marijuana.

AE=Adverse Event; NIDA=National Institute of Drug Abuse; QD=drug administered one time per day; sGaw=Specific Airway Conductance; THC=delta-9-tetrahydrocannbinol

U.S. Department of Justice—Drug Enforcement Administration

Schedule of Controlled Substances: Maintaining Marijuana in Schedule I of the Controlled Substances Act

Background, Data, and Analysis: Eight Factors Determinative of Control and Findings Pursuant to 21 U.S.C. 812(b)

Prepared by: Office of Diversion Control, Drug and Chemical Evaluation Section, Washington, DC 20537

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Background

On November 30, 2011, Governors Lincoln D. Chafee of Rhode Island and Christine O. Gregoire of Washington submitted a petition to the Drug Enforcement Administration (DEA) to initiate proceedings for a repeal of the rules or regulations that place marijuana[38] in schedule I of the Controlled Substances Act (CSA). The petition requests that marijuana[39] and "related items" be rescheduled in schedule II of the CSA. The petitioners claim that:

1. Cannabis has accepted medical use in the United States;
2. Cannabis is safe for use under medical supervision;
3. Cannabis for medical purposes has a relatively low potential for abuse, especially in comparison with other schedule II drugs.

The DEA accepted this petition for filing on January 30, 2012.

The Attorney General may by rule transfer a drug or other substance between schedules of the CSA if she finds that such drug or other substance has a potential for abuse, and makes the findings prescribed by 21 U.S.C. 812(b) for the schedule in which such drug is to be placed. 21 U.S.C. 811(a)(1). The Attorney General has delegated this responsibility to the Acting Administrator of the DEA. 28 CFR 0.100(b).

In accordance with 21 U.S.C. 811(b), after gathering the necessary data, the DEA submitted the petition and necessary data to the Department of Health and Human Services (HHS) on June 11, 2013, and requested that HHS provide a scientific and medical evaluation and scheduling recommendation for marijuana. In documents dated June 3 and June 25, 2015, the acting Assistant Secretary for Health of the HHS[40] recommended to the DEA that marijuana continue to be controlled in Schedule I of the CSA, and provided to the DEA its scientific and medical evaluation titled "Basis for the Recommendation for Maintaining Marijuana in Schedule I of the Controlled Substances Act." The HHS's recommendations are binding on the DEA as to scientific and medical matters. 21 U.S.C. 811(b).

Before initiating proceedings to reschedule a substance, the CSA requires the Acting Administrator to determine whether the HHS scheduling recommendation, scientific and medical evaluation, and "all other relevant data" constitute substantial evidence that the drug should be rescheduled as proposed. 21 U.S.C. 811(b). The Acting Administrator must determine whether there is substantial evidence to conclude that the drug meets the criteria for placement in another schedule based on the criteria set forth in 21 U.S.C. 812(b). The CSA requires that both the DEA and the HHS consider the eight factors specified by Congress in 21 U.S.C. 811(c). This document lays out those considerations and is organized according to the eight factors. As DEA sets forth in detail below, the evidence shows:

1. *Actual or relative potential for abuse.* Marijuana has a high potential for abuse. Preclinical and clinical data show that it has reinforcing effects characteristic of drugs of abuse. National databases on actual abuse show marijuana is the most widely abused drug, including significant numbers of substance abuse treatment admissions. Data on marijuana seizures show widespread availability and trafficking.

2. *Scientific evidence of its pharmacological effect.* The scientific understanding of marijuana, cannabinoid receptors, and the endocannabinoid system continues to be studied and elucidated. Marijuana produces various pharmacological effects, including subjective (*e.g.,* euphoria, dizziness, disinhibition), cardiovascular, acute and chronic respiratory, immune system, and prenatal exposure effects, as well as behavioral and cognitive impairment.

3. *Current scientific knowledge.* There is no currently accepted medical use for marijuana in the United States. Marijuana sources are derived from numerous cultivated strains and may have different levels of Δ^9-THC and other cannabinoids. Under the five-element test for currently accepted medical use discussed in more detail below and upheld by the Court of Appeals for the District of Columbia in *Alliance for Cannabis Therapeutics* v. *DEA,* 15 F.3d 1131, 1135 (D.C. Cir. 1994) (hereinafter "*ACT*"), there is no complete scientific analysis of marijuana's chemical components; there are not adequate safety studies; there are not adequate and well-controlled efficacy studies; there is not a consensus of medical opinion concerning medical applications of marijuana; and the scientific evidence regarding marijuana's safety and efficacy is not widely available. To date, scientific and medical research has not progressed to the point that marijuana has a currently accepted medical use, even under conditions where its use is severely restricted.

4. *History and current pattern of abuse.* Marijuana continues to be the most widely used illicit drug. In 2014, there were 22.2 million current users. There were also 2.6 million new users, most of whom were less than 18 years of age. During the same period, marijuana was the most frequently identified drug exhibit in federal, state, and local forensic laboratories.

5. *Scope, duration, and significance of abuse.* Abuse of marijuana is widespread and significant. In 2014, for example, an estimated 6.5 million people aged 12 or older used marijuana on a daily or almost daily basis over a 12-month period. In addition, a significant proportion of all admissions for substance abuse treatment are for marijuana/hashish as their primary drug of abuse. In 2013, 16.8% of all such admissions—281,991 over the course of the year—were for primary marijuana/hashish abuse.

6. *Risk, if any, to public health.* Together with the health risks outlined in terms of pharmacological effects above, public health risks from acute use of marijuana include impaired psychomotor performance, impaired driving, and impaired performance on tests of learning and associative

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[38] The Controlled Substances Act (CSA) defines marijuana as: "All parts of the plant *Cannabis sativa L.,* whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted there from), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination." 21 U.S.C. 802(16). Note that "marihuana" is the spelling used in the CSA. This document uses the spelling that is more common in current usage, "marijuana."

[39] Petitioners defined marijuana as all cultivated strains of cannabis.

[40] As set forth in a memorandum of understanding entered into by the HHS, the Food and Drug Administration (FDA), and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of the NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations.

processes. Chronic use of marijuana poses a number of other risks to the public health including physical as well as psychological dependence.

7. *Psychic or physiological dependence liability.* Long-term, heavy use of marijuana can lead to physical dependence and withdrawal following discontinuation, as well as psychic or psychological dependence. In addition, a significant proportion of all admissions for treatment for substance abuse are for primary marijuana abuse; in 2013, 16.8% of all admissions were for primary marijuana/hashish abuse, representing 281,991 individuals.

8. *Immediate precursor.* Marijuana is not an immediate precursor of any controlled substance.

As specified in 21 U.S.C. 812(b)(1), in order for a substance to be placed in schedule I, the Acting Administrator must find that:

A. The drug or other substance has a high potential for abuse.

B. The drug or other substance has no currently accepted medical use in treatment in the United States.

C. There is a lack of accepted safety for use of the drug or other substance under medical supervision.

To be classified in another schedule under the CSA (*e.g.*, II, III, IV, or V), a substance must have a "currently accepted medical use in treatment in the United States." 21 U.S.C. 812(b)(2)–(5). A substance also may be placed in schedule II if it is found to have "a currently accepted medical use with severe restrictions." 21 U.S.C. 812(b)(2). If a controlled substance has no such currently accepted medical use, it must be placed in schedule I. *See* Notice of Denial of Petition, 66 FR 20038 (Apr. 18, 2001) ("Congress established only one schedule—schedule I—for drugs of abuse with 'no currently accepted medical use in treatment in the United States' and 'lack of accepted safety for use . . . under medical supervision.' ").

A drug that is the subject of an approved new drug application (NDA) or abbreviated new drug application (ANDA) under Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), is considered to have a currently accepted medical use in treatment in the United States for purposes of the CSA. The HHS stated in its review, however, that FDA has not approved any NDA for marijuana for any indication.

In the absence of NDA or ANDA approval, DEA has established a five-element test for determining whether the drug has a currently accepted medical use in treatment in the United States. Under this test, a drug will be considered to have a currently accepted medical use only if the following five elements are satisfied:

1. The drug's chemistry is known and reproducible;
2. There are adequate safety studies;
3. There are adequate and well-controlled studies proving efficacy;
4. The drug is accepted by qualified experts; and
5. The scientific evidence is widely available.

(57 FR 10499, 10506 (March 26, 1992)). *See also ACT,* 15 F.3d at 1135.

As discussed in Factor 3, below, HHS concluded, and DEA agrees, that the scientific evidence is insufficient to demonstrate that marijuana has a currently accepted medical use under the five-element test. The evidence was insufficient in this regard also when the DEA considered petitions to reschedule marijuana in 1992 (57 FR 10499),[41] in 2001 (66 FR 20038), and in 2011 (76 FR 40552).[42] Little has changed since 2011 with respect to the lack of clinical evidence necessary to establish that marijuana has a currently accepted medical use. No studies have scientifically assessed the efficacy and full safety profile of marijuana for any specific medical condition.

The limited existing clinical evidence is not adequate to warrant rescheduling of marijuana under the CSA. To the contrary, the data in this scheduling review document show that marijuana continues to meet the criteria for schedule I control under the CSA for the following reasons:

1. Marijuana has a high potential for abuse.
2. Marijuana has no currently accepted medical use in treatment in the United States.
3. Marijuana lacks accepted safety for use under medical supervision.

Factor 1: The Drug's Actual or Relative Potential for Abuse

Marijuana is the most commonly abused illegal drug in the United States. It is also the most commonly used illicit drug by high school students in the United States. Further, marijuana is the most frequently identified drug by state, local and federal forensic laboratories. Marijuana's main psychoactive ingredient, Δ^9-tetrahydrocannabinol (Δ^9-THC),[43] is an effective reinforcer in laboratory animals, including primates and rodents. These animal studies both predict and support the observations that marijuana produces reinforcing effects in humans. Such reinforcing effects can account for the repeated abuse of marijuana.

A. Indicators of Abuse Potential

The HHS has concluded in its document, "Basis for the Recommendation for Maintaining Marijuana in Schedule I of the Controlled Substances Act," that marijuana has a high potential for abuse. The finding of "abuse potential" is critical for control under the Controlled Substances Act (CSA). Although the term is not defined in the CSA, guidance in determining abuse potential is provided in the legislative history of the Act (Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91–1444, 91st Cong., Sess. 2 (1970), reprinted in 1970 U.S.C.C.A.N. 4566, 4603). Accordingly, the following items are indicators that a drug or other substance has potential for abuse:

- *There is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or of the community; or*
- *There is significant diversion of the drug or drugs containing such a substance from legitimate drug channels; or*
- *Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice; or*
- *The drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.*

Of course, evidence of actual abuse of a substance is indicative that a drug has a potential for abuse.

In its recommendation, the HHS analyzed and evaluated data on marijuana as applied to each of the above four criteria. The analysis presented in the recommendation (HHS, 2015) is discussed below:

1. *There is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to*

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[41] *See Alliance for Cannabis Therapeutics* v. *DEA,* 15 F.3d 1131 (D.C. Cir. 1994).

[42] *See* Americans for Safe Access v. DEA, 706 F.3d 438 (D.C. Cir. 2013) (rhg den. 2013).

[43] The terms Δ^9-THC and THC are used interchangeably though out this document.

the safety of other individuals or of the community.

The HHS stated that some individuals are taking marijuana in amounts sufficient to create a hazard to their health and to the safety of other individuals and the community. Data from national databases on actual abuse of marijuana support the idea that a large number of individuals use marijuana. In its recommendation (HHS, 2015), the HHS presented data from the National Survey on Drug and Health (NSDUH) of the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Monitoring the Future (MTF) survey of the National Institute on Drug Abuse (NIDA), and the DEA has since updated this information. The most recent data from SAMHSA's NSDUH in 2014 reported that marijuana was the most used illicit drug. Among Americans aged 12 years and older, an estimated 22.2 million Americans used marijuana within the past month according to the 2014 NSDUH. In 2004, an estimated 14.6 million individuals reported using marijuana within the month prior to the study. The estimated rates in 2014 thus reflect an increase of approximately 7.6 million individuals over a 10-year period. According to the 2013 NSDUH report, an estimated 19.8 million individuals reported using marijuana. Thus, over a period of one year (2013 NSDUH–2014 NSDUH), there was an estimated increase of 2.4 million individuals in the United States using marijuana.

The results from the 2015 Monitoring the Future survey of 8th, 10th, and 12th grade students indicate that marijuana was the most widely used illicit drug in these age groups. Current monthly use was 6.5% of 8th graders, 14.8% of 10th graders, and 21.3% of 12th graders. The Treatment Episode Data Set (TEDS) in 2013 reported that marijuana abuse was the primary factor in 16.8 percent of non-private substance-abuse treatment facility admissions. In 2011, SAMHSA's Drug Abuse Warning Network (DAWN) reported that marijuana was mentioned in 36.4% (455,668 out of approximately 1.25 million) of illicit drug-related Emergency Department (ED) visits.

Data on the extent and scope of marijuana abuse are presented under Factors 4 and 5 of this analysis. Discussion of the health effects of marijuana is presented under Factor 2, and the assessment of risk to the public health posed by acute and chronic marijuana abuse is presented under Factor 6 of this analysis.

2. There is significant diversion of the drug or drugs containing such a substance from legitimate drug channels.

In accordance with the CSA, the only lawful source of marijuana in the United States is that produced and distributed for research purposes under the oversight of NIDA and in conformity with United States obligations under the Single Convention on Narcotic Drugs.[44] The HHS stated that there is a lack of significant diversion from legitimate drug sources, but that this is likely due to high availability of marijuana from illicit sources. Marijuana is not an FDA-approved drug product. Neither a New Drug Application (NDA) nor a Biologics License Application (BLA) has been approved for marketing in the United States. However, the marijuana used for nonclinical and clinical research represents a very small amount of the total amount of marijuana available in the United States and therefore information about marijuana diversion from legitimate sources is limited or not available.

The DEA notes that the magnitude of the demand for illicit marijuana is evidenced by information from a number of databases presented under Factor 4. Briefly, marijuana is the most commonly used illegal drug in the United States. It is also the most commonly used illicit drug by American high schoolers. Marijuana is the most frequently identified drug in state, local, and federal forensic laboratories, with increasing amounts of both domestically grown and of illicitly smuggled marijuana.

Given that marijuana has long been the most widely trafficked and abused controlled substance in the United States, and that all aspects of such illicit activity are entirely outside of the closed system of distribution mandated by the CSA, it may well be the case that there is little thought given to diverting marijuana from the small supplies produced for legitimate research purposes. Thus, the lack of data indicating diversion of marijuana from legitimate channels to the illicit market is not indicative of a lack of potential for abuse of the drug.

3. Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice.

The HHS stated that the FDA has not evaluated or approved an NDA or BLA for marijuana for any therapeutic indication. Consistent with federal law, therefore, an individual legitimately can take marijuana based on medical advice from a practitioner only by participating in research that is being conducted under an Investigational New Drug (IND) application. The HHS noted that there are several states as well as the District of Columbia which have passed laws allowing for individuals to use marijuana for purported "medical" use under certain circumstances, but data are not available yet to determine the number of individuals using marijuana under these state laws. Nonetheless, according to 2014 NSDUH data, 22.2 million American adults currently use marijuana (SAMHSA, 2015a). Based on the large number of individuals who use marijuana and the lack of an FDA-approved drug product, the HHS concluded that the majority of individuals using marijuana do so on their own initiative rather than by following medical advice from a licensed practitioner.

4. The drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

Marijuana and its primary psychoactive ingredient, Δ^9-THC, are controlled substances in schedule I under the CSA.

The HHS stated that one approved, marketed drug product contains synthetic Δ^9-THC, also known as dronabinol, and another approved, marketed drug product contains a cannabinoid-like synthetic compound that is structurally related to Δ^9-THC, the main active component in marijuana. Both products are controlled under the CSA.

Marinol is a schedule III drug product containing synthetic Δ^9-THC (dronabinol) formulated in sesame oil in soft gelatin capsules. Marinol was approved by the FDA in 1985 for the treatment of nausea and vomiting associated with cancer chemotherapy in patients who did not respond to conventional anti-emetic treatments. In 1992, FDA approved Marinol for the treatment of anorexia associated with weight loss in patients with acquired immunodeficiency syndrome (AIDS). Marinol was originally placed into schedule II and later rescheduled to schedule III under the CSA due to the low reports of abuse relative to marijuana.

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[44] *See* 76 FR 51403, 51409–51410 (2011) (discussing cannabis controls required under the Single Convention).

Cesamet is a drug product containing the schedule II substance nabilone, a synthetic substance structurally related to Δ^9-THC. Cesamet was approved for marketing by the FDA in 1985 for the treatment of nausea and vomiting associated with cancer chemotherapy. All other naturally occurring cannabinoids in marijuana and their synthetic equivalents with similar chemical structure and pharmacological activity are already included as schedule I drugs under the CSA.

B. Abuse Liability Studies

In addition to the indicators suggested by the CSA's legislative history, data as to preclinical and clinical abuse liability studies, as well as actual abuse, including clandestine manufacture, trafficking, and diversion from legitimate sources, are considered in this factor.

Abuse liability evaluations are obtained from studies in the scientific and medical literature. There are many preclinical measures of a drug's effects that when taken together provide an accurate prediction of the human abuse liability. Clinical studies of the subjective and reinforcing effects in humans and epidemiological studies provide quantitative data on abuse liability in humans and some indication of actual abuse trends. Both preclinical and clinical studies have clearly demonstrated that marijuana and Δ^9-THC possess the attributes associated with drugs of abuse: They function as a positive reinforcer to maintain drug-seeking behavior, they function as a discriminative stimulus, and they have dependence potential.

Preclinical and most clinical abuse liability studies have been conducted with the psychoactive constituents of marijuana, primarily Δ^9-THC and its metabolite, 11-hydroxy-Δ^9-THC. Δ^9-THC's subjective effects are considered to be the basis for marijuana's abuse liability. The following studies provide a summary of that data.

1. Preclinical Studies

Δ^9-THC, the primary psychoactive component in marijuana, is an effective reinforcer in laboratory animals, including primates and rodents, as these animals will self-administer Δ^9-THC. These animal studies both predict and support the observations that Δ^9-THC, whether smoked as marijuana or administered by other routes, produces reinforcing effects in humans. Such reinforcing effects can account for the repeated abuse of marijuana.

a. Drug Discrimination Studies

The drug discrimination paradigm is used as an animal model of human subjective effects (Solinas et al., 2006) and is a method where animals are able to indicate whether a test drug is able to produce physical or psychological changes similar to a known drug of abuse. Animals are trained to press one bar (in an operant chamber) when they receive a known drug of abuse and another bar when they receive a placebo. When a trained animal receives a test drug, if the drug is similar to the known drug of abuse, it will press the bar associated with the drug.

Discriminative stimulus effects of Δ^9-THC have specificity for the pharmacological effects of cannabinoids found in marijuana (Balster and Prescott, 1992; Browne and Weissman, 1981; Wiley et al., 1993; Wiley et al., 1995). As mentioned by the HHS, the discriminative stimulus effects of cannabinoids appear to be unique because abused drugs of other classes including stimulants, hallucinogens, opioids, benzodiazepines, barbiturates, NMDA antagonists, and antipsychotics do not fully substitute for Δ^9-THC.

Laboratory animals including monkeys (McMahon et al., 2009), mice (McMahon et al., 2008), and rats (Gold et al., 1992) are able to discriminate cannabinoids from other drugs and placebo. The major active metabolite of Δ^9-THC, 11-hydroxy-Δ^9-THC, generalizes to Δ^9-THC (Browne and Weissman, 1981). In addition, according to the HHS, twenty-two other cannabinoids found in marijuana also substitute for Δ^9-THC. At least one cannabinoid, CBD, does not substitute for Δ^9-THC in rats (Vann et al., 2008).

b. Self-Administration Studies

Animal self-administration behavior associated with a drug is a commonly used method for evaluating if the drug produces rewarding effects and for predicting abuse potential (Balster, 1991; Balster and Bigelow, 2003). Drugs that are self-administered by animals are likely to produce rewarding effects in humans. As mentioned in the HHS review document, earlier attempts to demonstrate self-administration of Δ^9-THC were unsuccessful and confounded by diet restrictions, animal restraint, and known analgesic activity of Δ^9-THC at testing doses (Tanda and Goldberg, 2003; Justinova et al., 2003). Self-administration of Δ^9-THC was first demonstrated by Tanda et al. (2000). Tanda et al. (2000) showed that squirrel monkeys that were initially trained to self-administer cocaine (30 μg/kg, i.v.) self-administered 2 μg/kg Δ^9-THC (i.v.) and at a rate of 30 injections per one hour session. Tanda et al. (2000) used a lower dose of Δ^9-THC that was rapidly delivered (0.2 ml injection over 200 ms) than in previous self-administration studies such that analgesic activity of Δ^9-THC was not a confounding factor. The authors also stated that the doses were comparable to those doses used by humans who smoke marijuana. A CB1 receptor antagonist (SR141716) blocked this rewarding effect of THC.

Justinova et al. (2003) were able to demonstrate self-administration of Δ^9-THC in drug-naïve squirrel monkeys (no previous exposure to other drugs). The authors tested the monkeys with several doses of Δ^9-THC (1, 2, 4, 8, and 16 μg/kg, i.v.) and found that the maximal rates of self-administration were observed with the 4 μg/kg/infusion. Subsequently, Braida et al. (2004) reported that rats will self-administer Δ^9-THC when delivered intracerebroventricularly (i.c.v.), but only at the lowest doses tested (0.01–0.02 μg/infusion, i.c.v.).

Self-administration behavior with Δ^9-THC was found to be antagonized in rats and squirrel monkeys by rimonabant (SR141716A, CB1 antagonist) and the opioid antagonists (naloxone and naltrexone) (Tanda et al., 2000; Braida et al., 2004; Justinova et al., 2004).

c. Conditioned Place Preference Studies

Conditioned place preference (CPP) is a behavioral assay where animals are given the opportunity to spend time in two distinct environments: one where they previously received a drug and one where they received a placebo. If the drug is reinforcing, animals in a drug-free state will choose to spend more time in the environment paired with the drug when both environments are presented simultaneously.

CPP has been demonstrated with Δ^9-THC in rats but only at low doses (0.075–1.0 mg/kg, i.p.; Braida et al., 2004). Rimonabant (0.25–1.0 mg/kg, i.p.) and naloxone (0.5–2.0 mg/kg, i.p.) antagonized Δ^9-THC-mediated CPP (Braida et al., 2004). However, in another study with rats, rimonabant was demonstrated to induce CPP at doses ranging from 0.25–3.0 mg/kg (Cheer et al., 2000). Mice without μ-opioid receptors did not exhibit CPP to Δ^9-THC (paired with 1 mg/kg Δ^9-THC, i.p.) (Ghozland et al., 2002).

2. Clinical Studies

In its scientific review (HHS, 2015), the HHS provided a list of common subjective psychoactive responses to cannabinoids based on information from several references (Adams and Martin, 1996; Gonzalez, 2007; Hollister, 1986;

Hollister, 1988; Institute of Medicine, 1982). Furthermore, Maldonado (2002) characterized these subjective responses as pleasurable to most humans and are generally associated with drug-seeking and/or drug-taking. Later studies (Scherrer et al., 2009; Zeiger et al., 2010) reported that high levels of positive psychoactive effects correlate with increased marijuana use, abuse, and dependence. The list of the common subjective psychoactive effects provided by the HHS (HHS, 2015) is presented below:

(1) *Disinhibition, relaxation, increased sociability, and talkativeness.*

(2) *Increased merriment and appetite, and even exhilaration at high doses.*

(3) *Enhanced sensory perception, which can generate an increased appreciation of music, art, and touch.*

(4) *Heightened imagination, which can lead to a subjective sense of increased creativity.*

(5) *Initial dizziness, nausea, tachycardia, facial flushing, dry mouth, and tremor.*

(6) *Disorganized thinking, inability to converse logically, time distortions, and short-term memory impairment.*

(7) *Ataxia and impaired judgment, which can impede driving ability or lead to an increase in risk-taking behavior.*

(8) *Illusions, delusions, and hallucinations that intensify with higher doses.*

(9) *Emotional lability, incongruity of affect, dysphoria, agitation, paranoia, confusion, drowsiness, and panic attacks, which are more common in inexperienced or high-dosed users.*

The HHS mentioned that marijuana users prefer higher concentrations of the principal psychoactive component (Δ^9-THC) over lower concentrations. In a clinical study with marijuana users (n = 12, usage ranged from once a month to 4 times a week), subjects were given a choice of 1.95% Δ^9-THC marijuana or 0.63% Δ^9-THC marijuana after sampling both marijuana cigarettes in two choice sessions. The marijuana cigarette with high THC was chosen in 21 out of 24 choice sessions or 87.5% of the time (Chait and Burke, 1994). Furthermore, in a double-blind study, frequent marijuana users (n = 11, usage at least 2 times per month with at least 100 occasions) when given a low-dose of oral Δ^9-THC (7.5 mg) were able to distinguish the psychoactive effects better than occasional users (n = 10, no use within the past 4 years with 10 or fewer lifetime uses) and also experienced fewer sedative effects (Kirk and de Wit, 1999).

Marijuana has also been recognized by scientific experts to have withdrawal symptoms (negative reinforcement) following moderate and heavy use. As discussed further in Factor 7, the DEA notes that the American Psychiatric Association's (APA) Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM–5) included a list of withdrawal symptoms following marijuana [cannabis] use (DSM–5, 2013).

C. Actual Abuse of Marijuana—National Databases Related to Marijuana Abuse and Trafficking

Marijuana continues to be the most widely used illicit drug. Evidence of actual abuse can be defined by episodes/mentions in databases indicative of abuse/dependence. The HHS provided in its recommendation (HHS, 2015) information relevant to actual abuse of marijuana including data results from the National Survey on Drug Use and Health (NSDUH), a Monitoring the Future (MTF) survey, the Drug Abuse Warning Network (DAWN), and the Treatment Episode Data Set (TEDS). These data sources provide quantitative information on many factors related to abuse of a particular substance, including incidence and patterns of use, and profile of the abuser of specific substances. The DEA is providing updated information from these databases in this discussion. The DEA also includes data on trafficking and illicit availability of marijuana from DEA databases including the National Forensic Laboratory Information System (NFLIS) and the National Seizure System (NSS), formerly the Federal-wide Drug Seizure System (FDSS), as well as other sources of data specific to marijuana, including the Potency Monitoring Project and the Domestic Cannabis Eradication and Suppression Program (DCE/SP).

1. National Survey on Drug Use and Health (NSDUH)

The National Survey on Drug Use and Health (NSDUH) is conducted annually by the Department of Health and Human Service's Substance Abuse and Mental Health Services Administration (SAMHSA). SAMHSA is the primary source of estimates of the prevalence and incidence of pharmaceutical drugs, illicit drugs, alcohol, and tobacco use in the United States. The survey is based on a nationally representative sample of the civilian, non-institutionalized population 12 years of age and older. The survey excludes homeless people who do not use shelters, active military personnel, and residents of institutional group quarters such as jails and hospitals.

According to the 2014 NSDUH report, marijuana was the most commonly used and abused illicit drug. That data showed that there were 22.2 million people who were past month users (8.4%) among those aged 12 and older in the United States. (Note: NSDUH figures on marijuana use include hashish use; the relative proportion of hashish use to marijuana use is very low.) Marijuana had the highest rate of past-year dependence or abuse in 2014. The NSDUH report estimates that 3.0 million people aged 12 or older used an illicit drug for the first time in 2014; a majority (70.3%) of these past year initiates reported that their first drug used was marijuana. Among those who began using illicit drugs in the past year, 65.6%, 70.3%, and 67.6% reported marijuana as the first illicit drug initiated in 2012, 2013, and 2014 respectively. In 2014, the average age of marijuana initiates among 12- to 49-year-olds was 18.5 years. These usage rates and demographics are relevant in light of the risks presented.

Marijuana had the highest rate of past year dependence or abuse of any illicit drug in 2014. The 2014 NSDUH report stated that 4.2 million persons were classified with substance dependence or abuse of marijuana in the past year (representing 1.6% of the total population aged 12 or older, and 59.0% of those classified with illicit drug dependence or abuse) based on criteria specified in the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM–IV).

Among past year marijuana users age 12 or older, 18.5% used marijuana on 300 or more days within the previous 12 months in 2014. This translates into 6.5 million people using marijuana on a daily or almost daily basis over a 12-month period, significantly more than the estimated 5.7 million daily or almost daily users in just the year before. Among past month marijuana users, 41.6% (9.2 million) used the drug on 20 or more days in the past month, a significant increase from the 8.1 million who used marijuana 20 days or more in 2013.

2. Monitoring the Future (MTF)

Monitoring the Future (MTF) is an ongoing study which is funded under a series of investigator-initiated competing research grants from the National Institute on Drug Abuse (NIDA). MTF tracks drug use trends among American adolescents in the 8th, 10th, and 12th grades. According to its 2015 survey results, marijuana was the most commonly used illicit drug, as was the case in previous years. Approximately 6.5% of 8th graders, 14.8% of 10th graders, and 21.3% of 12th graders surveyed in 2015 reported marijuana use during the past month prior to the survey. A number of high school students in 2015 also reported daily use in the past month, including 1.1%, 3.0%, and 6.0% of 8th, 10th, and 12th graders, respectively.

3. Drug Abuse Warning Network (DAWN), Emergency Department (ED) Visits

The Drug Abuse Warning Network (DAWN) is a public health surveillance system that monitors drug-related hospital emergency department (ED) visits to track the impact of drug use, misuse, and abuse in the United States. For the purposes of DAWN, the term "drug abuse" applies if the following conditions are met: (1) The case involved at least one of the following: use of an illegal drug, use of a legal drug contrary to directions, or inhalation of a non-pharmaceutical substance; and (2) the substance was used for one of the following reasons: Because of drug dependence, to commit suicide (or attempt to commit suicide), for recreational purposes, or to achieve other psychic effects. Importantly, many factors can influence the estimates of ED visits, including trends in overall use of a substance as well as trends in the reasons for ED usage. For instance, some drug users may visit EDs for life-threatening issues while others may visit to seek care for detoxification because they needed certification before entering treatment. Additionally, DAWN data do not distinguish the drug responsible for the ED visit from other drugs that may have been used concomitantly. As stated in a DAWN report, "Since marijuana/hashish is frequently present in combination with other drugs, the reason for the ED visit may be more relevant to the other drug(s) involved in the episode."

In 2011, marijuana was involved in 455,668 ED visits out of 2,462,948 total ED visits involving all abuse or misuse in the United States and out of 1.25 million visits involving abuse or misuse of illicit drugs (excluding alcohol-related visits), as estimated by DAWN. This is lower than the number of ED visits involving cocaine (505,224) and higher than the number of ED visits involving heroin (258,482) and stimulants (*e.g.*, amphetamine, methamphetamine) (159,840). Visits involving the other major illicit drugs, such as MDMA, GHB, LSD and other hallucinogens, PCP, and inhalants, were much less frequent, comparatively.

In young patients, marijuana is the illicit drug most frequently involved in ED visits, according to DAWN estimates, with 240.2 marijuana-related ED visits per 100,000 population ages 12 to 17, 443.8 per 100,000 population ages 18 to 20, and 446.9 per 100,000 population ages 21 to 24.

4. Treatment Episode Data Set (TEDS) System

The Treatment Episode Data Set (TEDS) system is part of the SAMHSA Drug and Alcohol Services Information System and is a national census of annual admissions to state licensed or certified, or administratively tracked, substance abuse treatment facilities. The TEDS system contains information on patient demographics and substance abuse problems of admissions to treatment for abuse of alcohol and/or drugs in facilities that report to state administrative data systems. For this database, the primary substance of abuse is defined as the main substance of abuse reported at the time of admission. TEDS also allows for the recording of two other substances of abuse (secondary and tertiary).

In 2011, the TEDS system included 1,928,792 admissions to substance abuse treatment; in 2012 there were 1,801,385 admissions; and in 2013 there were 1,683,451 admissions. Marijuana/hashish was the primary substance of abuse for 18.3% (352,397) of admissions in 2011; 17.5% (315,200) in 2012; and 16.8% (281,991) in 2013. Of the 281,991 admissions for marijuana/hashish treatment in 2013, 24.3% used marijuana/hashish daily. Among those treated for marijuana/hashish as the primary substance in 2013, 27.4% were ages 12 to 17 years and 29.7% were ages 18 to 24 years. Those admitted for marijuana/hashish were mostly male (72.6%) and non-Hispanic (82.2%). Non-hispanic whites (43.2%) represented the largest ethnic group of marijuana admissions.

5. Forensic Laboratory Data

Data on marijuana seizures from federal, state, and local forensic laboratories have indicated that there is significant trafficking of marijuana. The National Forensic Laboratory System (NFLIS) is a program sponsored by the Drug Enforcement Administration's Office of Diversion Control. NFLIS systematically collects drug identification results and associated information from drug exhibits encountered by law enforcement and analyzed in federal, state, and local forensic laboratories. NFLIS is a comprehensive information system that includes data from 278 individual forensic laboratories that report more than 91% of the drug caseload in the U.S. NFLIS captures data for all drugs and chemicals identified and reported by forensic laboratories. More than 1,700 unique substances are represented in the NFLIS database.

Data from NFLIS showed that marijuana was the most frequently identified drug in federal, state, and local laboratories from January 2004 through December 2014. Marijuana accounted for between 29.47% and 34.84% of all drug exhibits analyzed annually during that time frame (Table 1).

Table 1. NFLIS Federal, State and Local Forensic Laboratory Data of Marijuana Reports (other than hashish)

Year	Reports	Percent of Total Reports
2004	454,582	34.42%
2005	483,134	32.53%
2006	520,060	32.55%
2007	525,668	33.66%
2008	526,420	34.07%
2009	536,888	34.30%
2010	544,418	34.91%
2011	495,937	33.42%
2012	485,591	32.02%
2013	452,839	30.70%
2014	432,989	29.27%
2015*	341,162	26.73%

NFLIS database queried 03-23-2016, by date of submission, all drugs reported
*2015 data are still being reported to NFLIS due to normal lag time.

Since 2004, the total number of reports of marijuana and the amount of marijuana encountered federally has remained high (see data from Federal-wide Drug Seizure System and Domestic Cannabis Eradication and Suppression Program below).

6. Federal-Wide Drug Seizure System

The Federal-wide Drug Seizure System (FDSS) contains information about drug seizures made within the jurisdiction of the United States by the Drug Enforcement Administration, the Federal Bureau of Investigation, United States Customs and Border Protection, and United States Immigration and Customs Enforcement. It also records maritime seizures made by the United States Coast Guard. Drug seizures made by other Federal agencies are included in the FDSS database when drug evidence custody is transferred to one of the agencies identified above. FDSS is now incorporated into the National Seizure System (NSS), which is a repository for information on clandestine laboratory and contraband (chemicals and precursors, currency, drugs, equipment and weapons). FDSS reports total federal drug seizures [in kilograms (kg)] of substances such as cocaine, heroin, MDMA, methamphetamine, and cannabis (marijuana and hashish). The yearly volume of cannabis seized (Table 2), consistently exceeding a thousand metric tons per year, shows that cannabis is very widely trafficked in the United States.

Table 2. Total Federal Seizures of Cannabis (Expressed in Kg)
(Source: NSS, U.S. Seizures, EPIC System Portal, queried 08-05-2015)

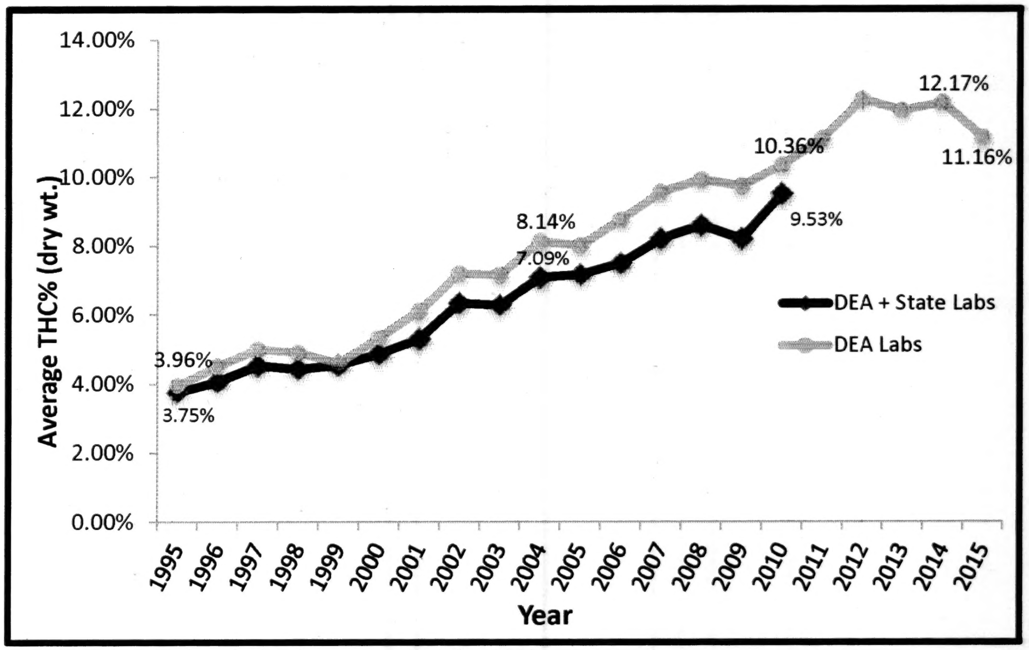
	2010	2011	2012	2013	2014
Cannabis	**4,071,328**	**3,622,256**	**2,756,439**	**2,622,494**	**1,768,277**
Marijuana	4,070,850	3,621,322	2,754,457	2,618,340	1,767,741
Hashish	478	934	1,982	4,154	536

7. Potency Monitoring Project

The University of Mississippi's Potency Monitoring Project (PMP), through a contract with the National Institute on Drug Abuse (NIDA), analyzes and compiles data on the Δ^9-THC concentrations of marijuana, hashish and hash oil samples provided by DEA regional laboratories and by state and local police agencies. After 2010, PMP has analyzed only marijuana samples provided by DEA regional laboratories. As indicated in Figure 1, the percentage of Δ^9-THC increased from 1995 to 2010 with an average THC content of 3.75% in 1995 and 9.53% in 2010. In examining marijuana samples only provided by DEA laboratories, the average Δ^9-THC content was 3.96% in 1995 in comparison to 11.16% in 2015.

Figure 1. Average Percentage of Δ^9-THC in Samples of Seized Marijuana (1995 – 2015)*

(Source: The University of Mississippi Potency Monitoring Program, Quarterly Report # 131)



*PMP discontinued analysis of state samples after 2010.

**Data for 2015 are incomplete. Figure 1 contains percentage of Δ^9-THC data through Dec. 22. Due to lack of funding, 4,177 samples haven't yet been analyzed.

8. The Domestic Cannabis Eradication and Suppression Program

The Domestic Cannabis Eradication and Suppression Program (DCE/SP) was established in 1979 to reduce the supply of domestically cultivated marijuana in the United States. The program was designed to serve as a partnership between federal, state, and local agencies. Only California and Hawaii were active participants in the program at its inception. However, by 1982 the program had expanded to 25 states and by 1985 all 50 states were participants. Cannabis is cultivated in remote locations and frequently on public lands and illicitly grown in all states. Data provided by the DCE/SP (Table 3) show that in the United States in 2014, there were 3,904,213 plants eradicated in outdoor cannabis cultivation areas compared to 2,597,798 plants in 2000. Significant quantities of marijuana were also eradicated from indoor cultivation operations. There were 396,620 indoor plants eradicated in 2014 compared to 217,105 eradicated in 2000.

Table 3. Domestic Cannabis Eradication, Outdoor and Indoor Plants Seized, 2000–2014 (Source: Domestic Cannabis Eradication/Suppression Program)

	2000	**2001**	**2002**	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
Outdoor	2,597,798	3,068,632	3,128,800	3,427,923	2,996,144	3,938,151	4,830,766	6,599,599	7,562,322	9,980,038	9,866,766	6,226,288	3,631,582	4,033,513	3,904,213
Indoor	217,105	236,128	213,040	223,183	203,896	270,935	400,892	434,728	450,986	414,604	462,419	509,231	302,377	361,727	396,620
Total	2,814,903	3,304,760	3,341,840	3,651,106	3,200,040	4,209,086	5,231,658	7,034,327	8,013,308	10,394,642	10,329,185	6,735,519	3,933,959	4,395,240	4,300,833

The recent statistics from these various surveys and databases show that marijuana continues to be the most commonly used illicit drug, with considerable rates of heavy abuse and dependence. They also show that marijuana is the most readily available illicit drug in the United States.

Petitioners' Major Comments in Relation to Factor 1 and the Government's Responses

(1) In Exhibit B, the petitioners compared the effects of marijuana to currently controlled schedule II substances and made repeated claims about the comparative effects.

The HHS noted that comparisons between marijuana and schedule II substances are difficult because of differences in the actions of different pharmacological classes of schedule II drugs in the CSA. The HHS notes that schedule II substances include stimulant-like drugs (*e.g.*, cocaine, amphetamine), opioids (*e.g.*, fentanyl, oxycodone), depressant drugs (*e.g.*, pentobarbital), dissociative anesthetics (*e.g.*, phencyclidine), and naturally occurring plant components (*e.g.*, coca leaves and poppy straw). The mechanism of action of Δ^9-THC and marijuana, which act primarily through the cannabinoid receptors (discussed further in Factor 2) are completely different from the above-mentioned classes of schedule II substances. The HHS concludes that the differences in the mechanisms of action in the various classes of schedule II substances make it inappropriate to compare the range of those substances with marijuana.

Furthermore, as noted by the HHS, many substances scheduled under the CSA are evaluated within the context of drug development using data submitted under a New Drug Application (NDA). However, the petitioners have not identified a specific indication for use of marijuana and therefore the HHS notes that an appropriate comparator based on indication cannot be identified.

(2) The petitioners indicated that the actual or relative potential of abuse of marijuana is low. The petitioners state, "*Some researchers claim that cannabis is not particularly addictive. Experts assert that cannabis's addictive potential parallels caffeine's.*" (Exhibit B, page 19, lines 20–21). Furthermore, petitioners stated that, "*Cannabis use indicates a lower likelihood of addiction and abuse potential as compared to other substances.*" (Exhibit B, page 22, lines 12–13).

Under the CSA, for a substance to be placed in schedule II, III, IV, or V, it must have a currently accepted medical use in treatment in the United States.[45] As DEA has previously stated, Congress established only one schedule, schedule I, for drugs of abuse with "no currently accepted medical use in treatment in the United States." 76 FR 40552 (2011). Thus, any attempt to compare the relative abuse potential of schedule I substance to that of a substance in another schedule is inconsequential since a schedule I substance must remain in schedule I until it has been found to have a currently accepted medical use in treatment in the United States.

Moreover, the petitioners failed to review the indicators of abuse potential, as discussed in the legislative history of the CSA. The petitioners did not use data on marijuana usage, diversion, psychoactive properties, and dependence in their evaluation of marijuana abuse potential. The HHS and the DEA discuss those indicators above in this factor. HHS's evaluation of the full range of data led HHS and DEA to conclude that marijuana has a high potential for abuse.

The petitioners, based on their review of a survey by Gore and Earleywine (2007), concluded that marijuana has a low abuse potential. Gore and Earleywine surveyed 746 mental health professionals and asked them to rate the addictiveness (based on a seven-point scale) of several drugs (heroin, nicotine, cocaine/crack, oxycodone, methamphetamine, amphetamine, caffeine, alcohol, and marijuana). The petitioners stated that the health professionals rated marijuana as least addictive of the drugs surveyed. The DEA notes that the survey cited by the petitioners is based on subjective opinions from health professionals.

(3) The petitioners mentioned that many of the cannabinoids in marijuana decrease the psychoactive effects of Δ^9-THC, and therefore marijuana lacks sufficient abuse potential for placement into schedule I. Further, the petitioners mentioned on page 4 in Exhibit B (lines 11–15), "*While the DEA considers cannabis a schedule I drug, it classifies dronabinol (Marinol) as schedule III. Dronabinol is 100 percent THC and is*

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[45] *See* Americans for Safe Access, 706 F.3d at 440.

potentially very psychoactive. Natural cannabis typically would be no more than 15 percent THC by weight. Thus it is inconsistent that cannabis, with 15 percent weight THC, remains a [s]chedule I drug, while dronabinol, at 100 percent THC, is schedule III."

The HHS addressed this issue by indicating that the modulating effects of the other cannabinoids in marijuana on Δ9-THC have not been demonstrated in controlled studies. The HHS and the DEA also note that the determination of the abuse potential of a substance considers not only psychoactive effects but also chemistry, pharmacology, pharmacokinetics, usage patterns, and diversion history among other measures.

Marinol (dronabinol in sesame oil) was rescheduled from schedule II to schedule III on July 2, 1999 (64 FR 35928, DEA 1999). In assessing Marinol, HHS compared Marinol to marijuana on several aspects of abuse potential and found that major differences between the two, such as formulation, availability, and usage, contribute to differences in abuse potential. The psychoactive effects from smoking are generally more rapid and intense than those that occur through oral administration (HHS, 2015; Wesson and Washburn, 1990; Hollister and Gillespie, 1973). Therefore, as concluded by both the HHS and the DEA, the delayed onset of action and longer duration of action from an oral dose of Marinol may contribute in limiting the abuse potential of Marinol relative to marijuana, which is most often smoked. The HHS also stated that the extraction and purification of dronabinol from the encapsulated sesame oil mixture of Marinol is highly complex and difficult, and that the presence of sesame oil mixture may preclude the smoking of Marinol-laced cigarettes.

Furthermore, marijuana and Marinol show significant differences in actual abuse and illicit trafficking. There have been no reports of abuse, diversion, or public health risks due to Marinol. In contrast, 22.2 million American adults report currently using marijuana (SAMHSA, 2015a). The DEA database, NFLIS, showed that marijuana was the most frequently identified drug in state and local forensic laboratories from January 2001 to December 2014 and indicates the high availability of marijuana. The differences in composition, actual abuse, and diversion contribute to the differences in scheduling between marijuana and Marinol.

Additionally, the FDA approved a New Drug Application (NDA) for Marinol, indicating a legitimate medical use for Marinol in the United States and allowing for Marinol to be rescheduled into schedule II and subsequently into schedule III of the CSA. The HHS mentioned that marijuana and Marinol differ on a wide variety of factors and these differences are major reasons for differential scheduling of marijuana and Marinol. Marijuana, as discussed more fully in Factors 3 and 6, does not have a currently accepted medical use in the United States, is highly abused, and has a lack of accepted safety.

Factor 2: Scientific Evidence of the Drug Pharmcological Effects, if Known

The HHS stated that there are large amounts of scientific data on the neurochemistry, mechanistic effects, toxicology, and pharmacology of marijuana. A scientific evaluation, as conducted by the HHS and the DEA, of marijuana's neurochemistry, human and animal behavioral pharmacology, central nervous system effects, and other pharmacological effects (*e.g.,* cardiovascular, immunological effects) is presented below.

Neurochemistry

Marijuana contains numerous constituents such as cannabinoids that have a variety of pharmacological actions. The petition defined marijuana as including all cannabis cultivated strains. The HHS stated that different marijuana samples derived from various cultivated strains may differ in their chemical constituents including Δ9-THC and other cannabinoids. Therefore marijuana products from different strains will have different biological and pharmacological effects. The chemical constituents of marijuana are discussed further in Factor 3.

The primary site of action for cannabinoids such as Δ9-THC is at the cannabinoid receptor. Two cannabinoid receptors, CB1 and CB2, have been identified and characterized (Battista et al., 2012; Piomelli, 2005) and are G-protein-coupled receptors. Activation of these inhibitory G-protein-coupled receptors inhibits adenylate cyclase activity, which prevents conversion of ATP to cyclic AMP. Cannabinoid receptor activation also results in inhibition of N- and P/Q-type calcium channels and activates inwardly rectifying potassium channels (Mackie et al., 1995; Twitchell et al., 1997). The HHS mentioned that inhibition of N-type calcium channels decreases neurotransmitter release and this may be the underlying mechanism in the ability of cannabinoids to inhibit acetylcholine, norepinephrine and glutamate from specific areas of the brain. These cellular actions may underlie the antinociceptive and psychoactive effects of cannabinoids. Δ9-THC acts as an agonist at cannabinoid receptors.

CB1 receptors are primarily found in the central nervous system and are located mainly in the basal ganglia, hippocampus and cerebellum of the brain (Howlett et al., 2004). CB1 receptors are also located in peripheral tissues such as the immune system (De Petrocellis and Di Marzo, 2009), but the concentration of CB1 receptors there is considerably lower than in the central nervous system (Herkenham et al., 1990; 1992). CB2 receptors are found primarily in the immune system and predominantly in B lymphocytes and natural killer cells (Bouaboula et al., 1993). CB2 receptors are also found in the central nervous system, primarily in the cerebellum and hippocampus (Gong et al., 2006).

Two endogenous ligands to the cannabinoid receptors, anandamide and arachidonyl glycerol (2–AG), were identified in 1992 (Devane et al., 1992) and 1995 (Mechoulam et al., 1995), respectively. Anandamide is a low-efficacy agonist (Brievogel and Childers, 2000) and 2–AG is a high efficacy agonist (Gonsiorek et al., 2000) to the cannabinoid receptors. These endogenous ligands are present in both the central nervous system and in the periphery (HHS, 2015).

Δ9-THC and cannabidiol (CBD) are two of the major cannabinoids in marijuana. Δ9-THC is the major psychoactive cannabinoid (Wachtel et al., 2002). Δ9-THC has similar affinity for CB1 and CB2 receptors and acts as a weak agonist at CB2 receptors. The HHS indicated that activation of CB1 receptors mediates psychotropic effects of cannabinoids. CBD has low affinity for both CB1 and CB2 receptors. CBD has antagonistic effects at CB1 receptors, and some inverse agonistic properties at CB2 receptors.

Animal Behavioral Effects

Animal abuse potential studies (drug discrimination, self-administration, conditioned place preference) are discussed more fully in Factor 1. Briefly, it was consistently demonstrated that Δ9-THC, the primary psychoactive component in marijuana, and other cannabinoids in marijuana have a distinct drug discriminative profile. In addition, animals self-administer Δ9-THC, and Δ9-THC in low doses produces conditioned place preference.

Central Nervous System Effects

Psychoactive Effects

The clinical psychoactive effects of marijuana are discussed more fully in Factor 1. Briefly, the psychoactive effects from marijuana use are considered pleasurable and associated with drug-seeking or drug-taking (HHS, 2015; Maldonado, 2002). Further, it was noted by HHS that marijuana users prefer higher concentrations of the principal psychoactive component (Δ^9-THC) over lower concentrations (HHS, 2015).

Studies have evaluated psychoactive effects of THC in the presence of high CBD, CBC, or CBN ratios. Even though some studies suggest that CBD may decrease some of Δ^9-THC's psychoactive effects, the HHS found that the ratios of CBD to Δ^9-THC administered in the studies were not comparable to the amounts found in marijuana used by most people (Dalton et al., 1976; Karniol et al., 1974; Zwardi et al., 1982). In fact, the CBD ratios in these studies are significantly higher than the CBD found in most marijuana currently found on the streets (Mehmedic et al., 2010). HHS indicated that most of the marijuana available on the street has a high THC and low CBD content and therefore any lessening of THC's psychoactive effects by CBD will not occur for most marijuana users (HHS, 2015). Dalton et al. (1976) reported that when volunteers smoked cigarettes with a ratio of 7 CBD to 1 Δ^9-THC (0.15 mg/kg CBD and 0.025 mg/kg Δ^9-THC), there was a significant decrease in ratings of acute subjective effects and achieving a "high" in comparison to smoking Δ^9-THC alone. In oral administration studies, the subjective effects and anxiety produced by combination of CBD and THC in a ratio of at least 1:2 CBD to Δ^9-THC (15, 30, 60 mg CBD to 30 mg Δ^9-THC; Karniol et al., 1974) or a ratio of 2:1 CBD to Δ^9-THC (1 mg/kg CBD to 0.5 mg/kg Δ^9-THC; Zuardi et al., 1982) are less than those produced by Δ^9-THC administered alone.

In one study (Ilan et al., 2005), the authors calculated the naturally occurring concentrations of CBC and CBD in marijuana cigarettes with either 1.8 or 3.6% Δ^9-THC by weight. The authors varied the concentrations of CBC and CBD for each concentration of Δ^9-THC in the marijuana cigarettes. Administrations in healthy marijuana users (n=23) consisted of either: (1) Low CBC (0.1% by weight) and low CBD (0.2% by weight); (2) high CBC (0.5% by weight) and low CBD; (3) low CBC and high CBD (1.0% by weight); or (4) high CBC and high CBD and the users were divided into low Δ^9-THC (1.8% by weight) and high Δ^9-THC (3.6% by weight) groups. Subjective psychoactive effects were significantly greater for all groups in comparison to placebo and there were no significant differences in effects among the treatments (Ilan et al., 2005).

The HHS also referred to a study with Δ^9-THC and cannabinol (CBN) (Karniol et al., 1975). In this study, oral administration of either 12.5, 25, or 50 mg CBN combined with 25 mg Δ^9-THC (ratio of at least 1:2 CBN to Δ^9-THC) significantly increased subjective psychoactive ratings of Δ^9-THC compared to Δ^9-THC alone (Karniol et al., 1975).

Behavioral Impairment

Several factors may influence marijuana's behavioral effects including the duration (chronic or short term), frequency (daily, weekly, or occasionally), and amount of use (heavy or moderate). Researchers have examined how long behavioral impairments persist following chronic marijuana use. These studies used self-reported histories of exposure duration, frequency, and amount of marijuana use, and administered several performance and cognitive tests at different time points following marijuana abstinence. According to HHS, behavioral impairments may persist for up to 28 days of abstinence in chronic marijuana users.

Psychoactive effects of marijuana can lead to behavioral impairment including cognitive decrements and decreased ability to operate motor vehicles (HHS, 2015). Block et al. (1992) evaluated cognitive measures in 48 healthy male subjects following smoking a marijuana cigarette that contained 2.57% or 19 mg Δ^9-THC by weight or placebo. Each subject participated in eight sessions (four sessions with marijuana; four sessions with placebo) and several cognitive and psychomotor tests were administered (*e.g.* verbal recall, facial recognition, text learning, reaction time). Marijuana significantly impaired performances in most of these cognitive and psychomotor tests (Block et al., 1992).

Ramaekers et al. (2006) reported that in 20 recreational users of marijuana, acute administration of 250 µg/kg and 500 µg/kg Δ^9-THC in smoked marijuana resulted in dose-dependent impairments in cognition, motor impulsivity, motor control (tracking impairments), and risk taking. In another study (Kurzthaler et al., 1999), when 290 µg/kg Δ^9-THC was administered via a smoked marijuana cigarette in 30 healthy volunteers with no history of substance abuse there were significant impairments of motor speed and accuracy. Furthermore, administration of 3.95% Δ^9-THC in a smoked marijuana cigarette increased the latency in a task of simulated braking in a vehicle (Liguori et al., 1998). The HHS noted that the motor impairments reported in these studies (Kurzthaler et al., 1999; Liguori et al., 1998) are critical skills needed for operating a vehicle.

As mentioned in the HHS document, some studies examined the persistence of the behavioral impairments immediately after marijuana administration. Some of marijuana's acute effects may still be present for at least 24 hours after the acute psychoactive effects have subsided. In a brief communication, Heishmann et al. (1990) reported that there were cognitive impairments (digit recall and arithmetic tasks) in two out of three experienced marijuana smokers for 24 hours after smoking marijuana cigarettes containing 2.57% Δ^9-THC. However, Fant et al. (1998) evaluated subjective effects and performance measures for up to 25 hours in 10 healthy males after exposure to either 1.8% or 3.6% Δ^9-THC in marijuana cigarettes. Peak decrements in subjective and performance measures were noted within 2 hours of marijuana exposure but there were minimal residual alterations in subjective or performance measures at 23–25 hours after exposure.

Persistence of behavioral impairments following repeated and chronic use of marijuana has also been investigated and was reviewed in the HHS document (HHS, 2015). In particular, researchers examined how long behavioral impairments last following chronic marijuana use. In studies examining persistence of effects in chronic and heavy marijuana users, there were significant decrements in cognitive and motor function tasks in all studies of up to 27 days, and in most studies at 28 days (Solowij et al., 2002; Messinis et al., 2006; Lisdahl and Price, 2012; Pope et al., 2002; Bolla et al., 2002; Bolla et al., 2005). In studies that followed heavy marijuana users for longer than 28 days and up to 20 years of marijuana abstinence, cognitive and psychomotor impairments were no longer detected (Fried et al., 2005; Lyons et al., 2004; Tait et al., 2011). For example, Fried et al. (2005) reported that after 3 months of abstinence from marijuana, any deficits in intelligence (IQ), memory, and processing speeds following heavy marijuana use were no longer observed (Fried et al., 2005). In a meta-analysis that examined non-acute and long-lasting effects of marijuana, any deficits in neurocognitive performance that were observed within the first month were no longer apparent after approximately one month of abstinence (Schreiner and Dunn, 2012). HHS further notes that in moderate marijuana users deficits in decision-making skills were not observed after 25 days of abstinence and additionally IQ, immediate memory and delayed memory skills were not significantly impacted as observed with heavy and chronic marijuana users (Fried et al., 2005; HHS, 2015).

As mentioned in the HHS document (HHS, 2015), the intensity and persistence of neurological impairment from chronic marijuana use also may be dependent on the age of first use. In two separate smaller scale studies (less than 100 participants per exposure group), Fontes et al. (2011) and Gruber et al. (2012) compared neurological function in early onset (chronic marijuana use prior to age 15 or 16) and late onset (chronic marijuana use after age 15 or 16) heavy marijuana users and found that there were significant deficits in executive neurological function in early onset users which were not observed or were less apparent in late onset users. In a prospective longitudinal birth cohort study following 1,037 individuals (Meier et al., 2012), a significant decrease in IQ and neuropsychological performance was observed in adolescent-onset users and persisted even after abstinence from marijuana for at least one year. However, Meier et al. (2012) reported in there was no significant change in IQ in adult-onset users.

The HHS noted that there is some evidence that the severity of the persistent neurological impairments may also be due in part to the amount of marijuana usage. In the study mentioned above, Gruber et al. (2012) found that the early onset users consumed three times as much marijuana per week and used it twice as often as late onset users. Meier et al. (2012) reported in their study, mentioned above, that there was a correlation between IQ deficits in adolescent onset users and the increased amount of marijuana used.

Behavioral Effects of Prenatal Exposure

In studies that examined effects of prenatal marijuana exposure, many of the pregnant women also used alcohol and tobacco in addition to marijuana. Even though other drugs were used in conjunction with marijuana, there is evidence of an association between heavy prenatal marijuana exposure and deficits in some cognitive function. There have been two prospective longitudinal birth cohort studies following individuals prenatally exposed to marijuana from birth until adulthood: The Ottawa Prenatal Prospective Study (OPPS; Fried et al., 1980), and the Maternal Health Practices and Child Development Project (MHPCD; Day et al., 1985). Both longitudinal studies report that heavy prenatal marijuana use is associated with decreased performance on tasks assessing memory, verbal and quantitative reasoning in 4-year-olds (Fried and Watkinson, 1990) and in 6 year olds (Goldschmidt et al., 2008). In subsequent studies with the OPPS cohort, deficits in sustained attention were reported in children ages 6 and 13–16 years (Fried et al., 1992; Fried, 2002) and deficits in executive neurological function were observed in 9- and 12-year-old children (Fried et al., 1998). DEA further notes that with the MHPCD cohort, follow-up studies reported an increased rate of delinquent behavior (Day et al., 2011) and decreased achievement test scores (Goldschmidt et al., 2012) at age 14. When the MHPCD cohort was followed to age 22, there was a marginal ($p = 0.06$) increase in psychosis with prenatal marijuana exposure and early onset of marijuana use (Day et al., 2015).

Association of Marijuana Use With Psychosis

There has been extensive research to determine whether marijuana usage is associated with development of schizophrenia or other psychoses, and the HHS indicated that the available data do not suggest a causative link between marijuana and the development of psychosis (HHS, 2015; Minozzi et al., 2010). As mentioned in the HHS review (HHS, 2015), numerous large scale longitudinal studies demonstrated that subjects who used marijuana do not have a greater incidence of psychotic diagnoses compared to non-marijuana users (van Os et al., 2002; Fergusson et al., 2005; Kuepper et al., 2011). Further, the HHS commented that when analyzing the available data examining the association between marijuana and psychosis, it is critical to differentiate whether the patients in a study are already diagnosed with psychosis or if the individuals have a limited number of symptoms associated with psychosis without qualifying for a diagnosis of the disorder.

As mentioned by the HHS, some of the studies examining the association between marijuana and psychosis utilized non-standard methods to categorize psychosis and these methods did not conform to the criteria in the Diagnostic and Statistical Manual (DSM–5) or the International Classification of Diseases (ICD–10) and would not be appropriate for use in evaluating the association between marijuana use and psychosis. For example, researchers characterized psychosis as "schizophrenic cluster" (Maremmani et al., 2004), "subclinical psychotic symptoms" (van Gastel et al., 2012), "pre-psychotic clinical high risk" (van der Meer et al., 2012), and symptoms related to "psychosis vulnerability" (Griffith-Lendering et al., 2012).

The HHS discussed an early epidemiological study conducted by Andreasson et al. (1987), which examined the link between psychosis and marijuana use. In this study, about 45,000 18- and 19-year-old male Swedish subjects provided detailed information on their drug-taking history and 274 of these subjects were diagnosed with schizophrenia over a 14-year period (1969–1983). Out of the 274 subjects diagnosed with psychosis, 21 individuals (7.7%) had used marijuana more than 50 times, while 197 individuals (72%) never used marijuana. As presented by the authors (Andreasson et al., 1987), individuals who claimed to take marijuana on more than 50 occasions were 6 times more likely to be diagnosed with schizophrenia than those who had never consumed the drug. The authors concluded that marijuana users who are vulnerable to developing psychoses are at the greatest risk for schizophrenia. In a 35 year follow up to the subjects evaluated in Andreasson et al. (1987), Manrique-Garcia et al. (2012) reported similar findings. In the follow up study, 354 individuals developed schizophrenia. Of those, 32 individuals (9%) had used marijuana more than 50 times and were 6.3 times more likely to develop schizophrenia. 255 of the 354 individuals (72%) never used marijuana.

The HHS also noted that many studies support the assertion that psychosis from marijuana usage may manifest only in individuals already predisposed to development of psychotic disorders. Marijuana use may precede diagnosis of psychosis (Schimmelmann et al., 2011), but most reports indicate that prodromal symptoms of schizophrenia are observed prior to marijuana use (Schiffman et al., 2005). In a review examining gene-environmental interaction between marijuana exposure and the development of psychosis, it was concluded that there is some evidence to support that marijuana use may influence the development of psychosis but only for susceptible individuals (Pelayo-Teran et al., 2012).

Degenhardt et al. (2003) modeled the prevalence of schizophrenia against marijuana use across eight birth cohorts in individuals born during 1940 to 1979 in Australia. Even though there was an increase in marijuana use in the adult subjects over this time period, there was not an increase in diagnoses of psychosis for these same subjects. The authors concluded that use of marijuana may increase schizophrenia only in persons vulnerable to developing psychosis.

Cardiovascular and Autonomic Effects

The HHS stated that acute use of marijuana causes an increase in heart rate (tachycardia) and may increase blood pressure (Capriotti et al., 1988; Benowitz and Jones, 1975). There is some evidence that associates the increased heart rate from Δ^9-THC exposure with excitation of the sympathetic and depression of the parasympathetic nervous systems (Malinowska et al., 2012). Tolerance to tachycardia develops with chronic exposure to marijuana (Jones, 2002; Sidney, 2002).

Prolonged exposure to Δ^9-THC results in a decrease in heart rate (bradycardia) and hypotension (Benowitz and Jones, 1975). These effects are thought to be mediated through peripherally located, presynaptic CB1 receptor inhibition of norepinephrine release with possible direct activation of vascular cannabinoid receptors (Wagner et al., 1998; Pacher et al., 2006).

As stated in the HHS recommendation (HHS, 2015), marijuana exposure causes orthostatic hypotension (fainting-like feeling; sudden drop in blood pressure upon standing up) and tolerance can develop to this effect upon repeated, chronic exposure (Jones, 2002). Tolerance to orthostatic hypotension is potentially related to plasma volume expansion, but tolerance does not develop to supine hypotensive effects (Benowitz and Jones, 1975).

Marijuana smoking, particularly by those with some degree of coronary artery or cerebrovascular disease, poses risks such as increased cardiac work, increased catecholamines and carboxyhemoglobin, myocardial infarction and postural hypotension (Benowitz and Jones, 1981; Hollister, 1988; Mittleman et al., 2001; Malinowska et al., 2012). However, electrocardiographic changes were minimal after administration of large cumulative doses of Δ^9-THC (Benowitz and Jones, 1975).

The DEA notes two recent reports that reviewed several case studies on marijuana and cardiovascular complications (Panayiotides, 2015; Hackam, 2015). Panayiotides (2015) reported that approximately 25.6% of the cardiovascular cases from marijuana use resulted in death from data provided by the French Addictovigilance Network during the period of 2006–2010. Several case studies on marijuana usage and cardiovascular events were discussed and it was concluded that although a causal link cannot be established due to not knowing exact amounts of marijuana used in the cases and confounding variables, the available evidence supports a link between marijuana and cardiotoxicity. Hackham (2015) reviewed 34 case reports or case series reports of marijuana and stroke/ischemia in 64 stroke patients and reported that in 81% of the cases there was a temporal relationship between marijuana usage and stroke or ischemic event. The author concluded that collective analysis of the case reports supports a causal link between marijuana use and stroke.

Respiratory Effects

The HHS stated that transient bronchodilation is the most typical respiratory effect of acute exposure to marijuana (Gong et al., 1984). In a recent longitudinal study, information on marijuana use and pulmonary data function were collected from 5,115 individuals over 20 years from 4 communities in the United States (Oakland, CA; Chicago, IL; Minneapolis, MN; Birmingham, AL) (Pletcher et al., 2012). Of the 5,115 individuals, 795 individuals reported use of only marijuana (without tobacco). The authors reported that occasional use of marijuana (7 joint-years for lifetime or 1 joint/day for 7 years or 1 joint/week for 49 years) does not adversely affect pulmonary function. Pletcher et al. (2012) further concluded that there is some preliminary evidence suggesting that heavy marijuana use may have a detrimental effect on pulmonary function, but the sample size of heavy marijuana users in the study was too small. Further, as mentioned in the HHS recommendation document (HHS, 2015), long-term use of marijuana may lead to chronic cough, increased sputum, as well as increased frequency of chronic bronchitis and pharyngitis (Adams and Martin, 1996; Hollister, 1986).

The HHS stated that the evidence that marijuana may lead to cancer of the respiratory system is inconsistent, with some studies suggesting a positive correlation while others do not (Lee and Hancox, 2011; Tashkin, 2005). The HHS noted a case series that reported lung cancer occurrences in three marijuana smokers (age range 31–37 years) with no history of tobacco smoking (Fung et al., 1999). Furthermore, in a case-control study (n = 173 individuals with squamous cell carcinoma of the head and neck; n = 176 controls; Zhang et al., 1999), prevalence of marijuana use was 9.7% in controls and 13.9% in cases and the authors reported that marijuana use may dose-dependently interact with mutagenic sensitivity, cigarette smoking, and alcohol use to increase risk associated with head and neck cancers (Zhang et al., 1999). However, in a large clinical study with 1,650 subjects, no positive correlation was found between marijuana use and lung cancer (Tashkin et al., 2006). This finding held true regardless of the extent of marijuana use when both tobacco use and other potential confounding factors were controlled. The HHS concluded that new evidence suggests that the effects of smoking marijuana on respiratory function and cancer are different from the effects of smoking tobacco (Lee and Hancox, 2011).

The DEA further notes the publication of recent review articles critically evaluating the association between marijuana and lung cancer. Most of the reviews agree that the association is weak or inconsistent (Huang et al., 2015; Zhang et al., 2015; Gates et al., 2014; Hall and Degenhardt, 2014). Huang et al. (2015) identified and reviewed six studies evaluating the association between marijuana use and lung cancer and the authors concluded that an association is not supported most likely due to the small amounts of marijuana smoked in comparison to tobacco. Zhang et al. (2015) examined six case control studies from the US, UK, New Zealand, and Canada within the International Lung Cancer Consortium and found that there was a weak association between smoking marijuana and lung cancer in individuals who never smoked tobacco, but precision of the association was low at high marijuana exposure levels. Hall and Degenhardt (2014) noted that even though marijuana smoke contains several of the same carcinogens and co-carcinogens as tobacco smoke (Roth et al., 1998) and has been found to be mutagenic and carcinogenic in the mouse skin test, epidemiological studies have been inconsistent, but more consistent positive associations have been reported in case control studies. Finally Gates et al. (2014), reviewed the studies evaluating marijuana use and lung cancer and concluded that there is evidence that marijuana produces changes in the respiratory system (precursors to cancer) that could lead to lung cancer, but overall association is weak between marijuana use and lung cancer especially when controlling for tobacco use.

Endocrine System

Reproductive Hormones

The HHS stated that administration of marijuana to humans does not consistently alter the endocrine system. In a controlled human exposure study (n = 4 males), subjects were acutely administered smoked marijuana containing 2.8% Δ^9-THC or placebo and an immediate significant decrease in luteinizing hormone and an increase in cortisol was reported in the subjects that smoked marijuana (Cone et al., 1986). Furthermore, as cited by the HHS, two later studies (Dax et al., 1989; Block et al., 1991) reported no changes in hormone levels. Dax et al. (1989) recruited male volunteers (n = 17) that were occasional or heavy users of marijuana. Following exposure to smoked Δ^9-THC (18 mg/cigarette) or oral Δ^9-THC (10 mg three times per day for three days and on the morning of the fourth day), the subjects in that study showed no changes in plasma adrenocorticotropic hormone (ACTH), cortisol, prolactin, luteinizing hormone, or testosterone levels. Additionally, Block et al. (1991) compared plasma hormone levels amongst non-users as well as infrequent, moderate, and frequent users of marijuana (n = 93 men and 56 women) and found that chronic use of marijuana (infrequent, moderate, and frequent users) did not significantly alter concentrations of testosterone, luteinizing hormone, follicle stimulating hormone, prolactin, or cortisol.

The HHS noted that there is a discrepancy in the effect of marijuana on female reproductive system functionality between animals and humans (HHS, 2015). Female rhesus monkeys that were administered 2.5 mg/kg Δ^9-THC, i.m., during days 1–18 of the menstrual cycle had reduced progesterone levels and ovulation was suppressed (Asch et al., 1981). However, women who smoked marijuana (1 gram marijuana cigarette with 1.8% Δ^9-THC) during the periovulatory period (24–36 hours prior to ovulation) did not exhibit changes in reproductive hormone levels or their menstrual cycles (Mendelson and Mello, 1984). In a review article by Brown and Dobs (2002), the authors state that endocrine changes observed with marijuana are no longer observed with chronic administration and this may be due to drug tolerance.

Reproductive Cancers

The HHS stated that recent studies support a possible association between frequent, long-term marijuana use and increased risk of testicular germ cell tumors. In a hospital-based case-control study, the frequency of marijuana use was compared between testicular germ cell tumor (TGCT) patients (n = 187) and controls (n = 148) (Trabert et al., 2011).

TGCT patients were more likely to be frequent marijuana users than controls with an odds ratio (OR) of 2.2 (95% confidence limits of 1.0–5.1) and were less likely to be infrequent or short-term users with odds ratios of 0.5 and 0.6, respectively in comparison to controls (Trabert et al., 2011). The DEA further notes that in two population-based case-control studies (Daling et al., 2009; Lacson et al., 2012), marijuana use was compared between patients diagnosed with TGCT and matched controls in Washington State or Los Angeles County. In both studies, it was reported that TCGT patients were twice as likely as controls to use marijuana. Authors of both studies concluded that marijuana use is associated with an elevated risk of TGCT (Daling et al., 2009; Lacson et al., 2012).

The HHS cited a study (Sarfaraz et al., 2005) demonstrating that WIN 55,212–2 (a mixed CB1/CB2 agonist) induces apoptosis (one form of cell death) in prostate cancer cells and decreases expression of androgen receptors and prostate specific antigens, suggesting a potential therapeutic value for cannabinoid agonists in the treatment of prostate cancer, an androgen-stimulated type of carcinoma.

Other Hormones (*e.g.* Thyroid, Appetite)

In more recent studies, as cited by the HHS, chronic marijuana use by subjects (n = 39) characterized as dependent on marijuana according to the ICD–10 criteria did not affect serum levels of thyroid hormones: TSH (thyrotropin), T4 (thyroxine), and T3 (triiodothyronine) (Bonnet, 2013). With respect to appetite hormones, in a pilot study with HIV-positive males, smoking marijuana dose-dependently increased plasma levels of ghrelin and leptin and decreased plasma levels of peptide YY (Riggs et al., 2012).

The HHS stated that Δ^9-THC reduces binding of the corticosteroid dexamethasone in hippocampal tissue from adrenalectomized rats and acute Δ^9-THC releases corticosterone, with tolerance developing to this effect with chronic administration (Eldridge et al., 1991). These data suggest that Δ^9-THC may interact with the glucocorticoid receptor system.

Immune System

The HHS stated that cannabinoids alter immune function but that there can be differences between the effects of synthetic, natural, and endogenous cannabinoids (Croxford and Yamamura, 2005; Tanasescu and Constantinescu, 2010).

The HHS noted that there are conflicting results in animal and human studies with respect to cannabinoid effects on immune functioning in subjects with compromised immune systems. Abrams et al. (2003) examined the effects of marijuana and Δ^9-THC in 62 HIV–1-infected patients. Subjects received one of three treatments, three times a day: smoked marijuana cigarette containing 3.95% Δ^9-THC, oral tablet containing Δ^9-THC (2.5 mg oral dronabinol), or oral placebo. There were no changes in CD4+ and CD8+ cell counts, HIV RNA levels, or protease inhibitor levels in any of the treatment groups (Abrams et al., 2003). Therefore, use of cannabinoids showed no short-term adverse virologic effects in individuals with compromised immune systems. Conversely, Roth et al. (2005) reported that in immunodeficient mice implanted with human blood cells infected with HIV, exposure to Δ^9-THC *in vivo* suppresses immune function, increases HIV co-receptor expression, and acts as a cofactor to enhance HIV replication.

The DEA notes two recent clinical studies reporting a decrease in cytokine and interleukin levels following marijuana use. Keen et al. (2014) compared the differences in the levels of IL–6 (interleukin-6), a proinflammatory cytokine, amongst non-drug users (n = 78), marijuana only users (n = 46) and marijuana plus other drug users (n = 45) in a community-based sample of middle-aged African Americans (Keen et al., 2014). After adjusting for confounders, analyses revealed that lifetime marijuana only users had significantly lower IL–6 levels than the nonuser group. Further, Sexton et al. (2014) compared several immune parameters in healthy individuals and subjects with multiple sclerosis (MS) and found that the chronic use of marijuana resulted in reduced monocyte migration, and decreased levels of CCL2 and IL–17 in both healthy and MS groups.

The DEA also notes a review suggesting that Δ^9-THC suppresses the immune responses in experimental animal models and *in vitro* and that these changes may be primarily mediated through the CB2 cannabinoid receptor (Eisenstein and Meissler, 2015).

Petitioners' Major Comments in Relation to Factor 2 and the Government's Responses

(1) The petitioners state that *"[m]edical use of cannabis is considered safe."* (Exhibit B, page 7); and that *"[t]here are adequate and well-controlled studies proving the medical efficacy of cannabis."* (Exhibit B, page 10). The petitioners also allege that *"Cannabis is safer than current, legal Schedule II opiate drugs"* and that it presents milder side effects (Exhibit B, page 9–10).

As detailed in the HHS review and as discussed later in this document (see Factor 3), there are neither adequate safety studies nor adequate, well-controlled studies proving marijuana's efficacy. The DEA notes that neither the CSA nor established scheduling criteria suggest that the HHS and DEA should consider the relative safety profiles of drugs when determining the proper schedule. To the extent that the petitioners were referring to abuse and dependence liability, this document discusses those effects in factors 1, 4, and 7.

(2) The petitioners state that *"scientific evidence regarding the safety and efficacy of cannabis is readily available directly from the National Library of Medicine."* (Exhibit B, page 14).

The government agrees that many articles *discuss* marijuana and its constituents. Yet, these articles in no way demonstrate that marijuana is safe and effective for the treatment of any disease or condition. As mentioned in the HHS review and as discussed later in this document (see Factor 3), the current research does not provide adequate detailed scientific evidence regarding chemistry, pharmacology, toxicology, and effectiveness derived from well-controlled clinical investigations to permit a conclusion that marijuana is safe and effective for treating a specific, recognized disorder.

(3) The petitioners mentioned on page 9 of exhibit B that *"[t]here has never been a lethal overdose of marijuana reported in humans"* and that *"[t]here is no known LD50 for any form of cannabis."*

As more fully discussed in Factor 3 below, the HHS and DEA conclude that there are not adequate studies to determine the safety of marijuana. As discussed in the HHS document and below, the determination of safety is more complex than a mere determination of the rate or likelihood of death. Moreover, the lack of overdose deaths attributed to a drug is not evidence that the drug is safe for medical use.

Factor 3: The State of the Current Scientific Knowledge Regarding the Drug or Substance

Chemistry

The HHS stated that marijuana, also known as *Cannabis sativa L.*, is part of the Cannabaceae plant family and is one of the oldest cultivated crops. The term "marijuana" is generally used to refer to a mixture of the dried flowering tops and leaves from *Cannabis*. Marijuana users primarily smoke the marijuana leaves, but individuals also ingest marijuana through food infused with marijuana and its extracts. *Cannabis sativa* is the primary species of *Cannabis* that is illegally marketed in the United States. Marijuana is one of three major derivatives sold as separate illicit products, the other two being hashish and hash oil. Hashish is composed of the dried and compressed cannabinoid-rich resinous material of *Cannabis* and is found as balls and cakes as well as other forms. Individuals may break off pieces and place them into a pipe to smoke. Hash oil, a viscous brown or amber colored liquid, is produced by solvent extraction of cannabinoids from *Cannabis* and contains approximately 50% cannabinoids. One to two drops of hash oil on a cigarette has been reported to produce the equivalent of a single marijuana cigarette (DEA, 2015).

The HHS indicated in its evaluation that the petitioners defined marijuana as including all *Cannabis* cultivated strains. However, different marijuana samples are derived from numerous cultivated strains and may have different chemical compositions including levels of Δ^9-THC and other cannabinoids (Appendino et al., 2011). A consequence of having different chemical compositions in the various marijuana samples is that there will be significant differences in safety, biological, pharmacological, and toxicological profiles and therefore, according to the HHS, all *Cannabis* strains cannot be considered collectively because of the variations in chemical composition. Furthermore, the concentration of Δ^9-THC and other cannabinoids present in marijuana may vary due to growing conditions and processing of the plant after harvesting. For example, the plant parts collected such as flowers, leaves and stems can influence marijuana's potency, quality, and purity (Adams and Martin, 1996; Agurell et al., 1984; Mechoulam, 1973). Variations in marijuana harvesting have resulted in potencies ranging from a low of 1 to 2% up to a high of 17% as indicated by cannabinoid content. The concentration of Δ^9-THC averages approximately 12% by weight in a typical marijuana mixture of leaves and stems. However, some specifically grown and selected marijuana samples can contain 15% or greater Δ^9-THC (Appendino et al., 2011). As a result, the Δ^9-THC content in a 1 gram marijuana cigarette can range from as little as 3 milligrams to 150 milligrams or more. In a systematic review conducted by Cascini et al. (2012), it was reported that marijuana's Δ^9-THC content has increased significantly from 1979–2009.

Since there is considerable variability in the cannabinoid concentrations and chemical constituency among marijuana samples, the interpretation of clinical data with marijuana is complicated. A primary issue is the lack of consistent concentrations of Δ^9-THC and other substances in marijuana which complicates the interpretation of the effects of different marijuana constituents. An added issue is that the non-cannabinoid components in marijuana may potentially modify the overall pharmacological and toxicological properties of various marijuana strains and products.

Various *Cannabis* strains contain more than 525 identified natural constituents including cannabinoids, 21 (or 22) carbon terpenoids found in the plant, as well as their carboxylic acids, analogues, and transformation products (Agurell et al., 1984; 1986; Mechoulam, 1973; Appendino et al., 2011). To date, more than 100 cannabinoids have been characterized (ElSohly and Slade, 2005; Radwan et al., 2009; Appendino et al., 2011), and most major cannabinoid compounds occurring naturally have been identified. There are still new and comparably more minor cannabinoids being characterized (Pollastro et al., 2011). The majority of the cannabinoids are found in *Cannabis*. One study reported accumulation of two cannabinoids, cannabigerol and its corresponding acid, in *Helichrysum* (*H. umbraculigerum*) which is a non-*Cannabis* source (Appendino et al., 2011).

Of the cannabinoids found in marijuana, Δ^9-THC (previously known as Δ^1-THC) and delta-8-tetrahydrocannabinol (Δ^8-THC, Δ^6-THC) have been demonstrated to produce marijuana's psychoactive effects. Psychoactive effects from marijuana usage have been mainly attributed to Δ^9-THC because Δ^9-THC is present in significantly more quantities than Δ^8-THC in most marijuana varieties. There are only a few marijuana strains that contain Δ^8-THC in significant amounts (Hively et al., 1966). Δ^9-THC is an optically active resinous substance that is extremely lipophilic. The chemical name for Δ^9-THC is (6a*R*-trans)-6a,7,8,10a-tetrahydro-6,6,9-trimethyl-3-pentyl-6*H*-dibenzo-[b,d]pyran-1-ol, or (−)-delta9-(trans)-tetrahydrocannabinol. The (−)-trans Δ^9-THC isomer is pharmacologically 6 to 100 times more potent than the (+)-trans isomer (Dewey et al., 1984).

Other relatively well-characterized cannabinoids present in marijuana include cannabidiol (CBD), cannabichromene (CBC), and cannabinol (CBN). CBD and CBC are major cannabinoids in marijuana and are both lipophilic. The chemical name for CBD is 2-[(1*R*,6*R*)-3-methyl-6-prop-1-en-2-ylcyclohex-2-en-1-yl]-5-pentylbenzene-1,3-diol and the chemical name for CBC is 2-methyl-2-(4-methylpent-3-enyl)-7-pentyl-5-chromenol. CBN is a minor naturally-occurring cannabinoid with weak psychoactivity and is also a major metabolite of Δ^9-THC. The chemical name for CBN is 6,6,9-trimethyl-3-pentyl-benzo[c]chromen-1-ol.

In summary, marijuana has several strains with high variability in the concentrations of Δ^9-THC, the main psychoactive component, as well as other cannabinoids and compounds. Marijuana is not a single chemical and does not have a consistent and reproducible chemical profile with predictable or consistent clinical effects. In the HHS recommendation for marijuana scheduling (HHS, 2015), it was recommended that investigators consult a guidance for industry entitled, *Botanical Drug Products,*[46] which provides information on the approval of botanical drug products. Specifically, in order to investigate marijuana in support of a New Drug Application (NDA), clinical studies under an Investigational New Drug (IND) application should include "consistent batches of a particular marijuana product for [a] particular disease." (HHS, 2015). Furthermore, the HHS noted that investigators must provide data meeting the requirements for new drug approval as stipulated in 21 CFR 314.50 (HHS, 2015).

Human Pharmacokinetics

Pharmacokinetics of marijuana in humans is dependent on the route of administration and formulation (Adams and Martin, 1996; Agurell et al., 1984; Agurell et al., 1986). Individuals primarily smoke marijuana as a cigarette (weighing between 0.5 and 1 gram) or in a pipe. More recently, vaporizers have been used as another means for individuals to inhale marijuana. Marijuana may also be ingested orally in foods or as an extract in ethanol or other solvents. Pharmacokinetic studies with marijuana focused on evaluating the absorption, metabolism, and elimination profile of Δ^9-THC and other cannabinoids (Adams and Martin, 1996; Agurell et al., 1984; Agurell et al., 1986).

Absorption and Distribution of Inhaled Marijuana Smoke

There is high variability in the pharmacokinetics of Δ^9-THC and other cannabinoids from smoked marijuana due to differences in individual smoking behavior even under controlled experimental conditions (Agurell et al., 1986; Herning et al., 1986; Huestis et al., 1992a). Experienced marijuana users can titrate and regulate the dose by holding marijuana smoke in their lungs for an extended period of time resulting in increased psychoactive effects by prolonging absorption of the smoke. This property may also help explain why there is a poor correlation between venous levels of Δ^9-THC and the intensity of effects and intoxication (Agurell et al., 1986; Barnett et al., 1985; Huestis et al., 1992a). The HHS recommended that puff and inhalation volumes should be tracked in experimental studies because the concentration of cannabinoids can vary at different stages of smoking.

Δ^9-THC from smoked marijuana is rapidly absorbed within seconds. Psychoactive effects are observed immediately following absorption with measurable neurological and behavioral changes for up to 6 hours (Grotenhermen, 2003; Hollister, 1986; Hollister, 1988). Δ^9-THC is distributed to the brain in a rapid and efficient manner. Bioavailability of Δ^9-THC from marijuana (from a cigarette or pipe) ranges from 1 to 24% with the fraction absorbed rarely exceeding 10 to 20% (Agurell et al., 1986; Hollister, 1988). The low and variable bioavailability of Δ^9-THC is due to loss in side-stream smoke, variation in individual smoking behaviors and experience, incomplete absorption of inhaled smoke, and metabolism in lungs (Herning et al., 1986; Johansson et al., 1989). After cessation of smoking, Δ^9-THC venous levels decline within minutes and continue to decline to about 5% to 10% of the peak level within an hour (Agurell et al., 1986; Huestis et al., 1992a; Huestis et al., 1992b).

Absorption and Distribution of Orally Administered Marijuana

Following oral administration of Δ^9-THC or marijuana, onset of effects start within 30 to 90 minutes, peak after 2 to 3 hours and effects remain for 4 to 12 hours (Grotenhermen, 2003; Adams and Martin, 1996; Agurell et al., 1984; Agurell et al., 1986). Dose titration of Δ^9-THC from orally ingested marijuana is difficult for users in comparison to smoked or inhaled marijuana due to the delay in the onset of effects. Oral bioavailability of Δ^9-THC, either in its pure form or in marijuana, is low and variable with a range from 5% to 20% (Agurell et al., 1984; Agurell et al., 1986). There is also inter- and intra-subject variability of orally administered Δ^9-THC under experimental conditions and even under repeated dosing experiments (HHS, 2015). The HHS noted that in bioavailability studies using radiolabeled Δ^9-THC, Δ^9-THC plasma levels following oral administration of Δ^9-THC were low relative to plasma levels after inhaled or intravenously administered Δ^9-THC. The low and variable bioavailability of orally administered Δ^9-THC is due to first pass hepatic elimination from blood and erratic absorption from stomach and bowel (HHS, 2015).

Metabolism and Excretion of Cannabinoids From Marijuana

Studies evaluating cannabinoid metabolism and excretion focused on Δ^9-THC because it is the primary psychoactive component in marijuana. Δ^9-THC is metabolized via microsomal hydroxylation and oxidation to both active and inactive metabolites (Lemberger et al., 1970; Lemberger et al., 1972a; Lemberger et al., 1972b; Agurell et al., 1986; Hollister, 1988). Metabolism of Δ^9-THC is consistent among frequent and infrequent marijuana users (Agurell et al., 1986). The primary active metabolite of Δ^9-THC following oral ingestion is 11-hydroxy-Δ^9-THC which is equipotent to Δ^9-THC in producing marijuana-like subjective effects (Agurell et al., 1986; Lemberger and Rubin, 1975). Metabolite levels following oral administration may be greater than that of Δ^9-THC and may contribute greatly to the pharmacological effects of oral Δ^9-THC or marijuana.

Plasma clearance of Δ^9-THC approximates hepatic blood flow at a rate of approximately 950 ml/min or greater. Rapid clearance of Δ^9-THC from blood is primarily due to redistribution to other tissues in the body rather than to metabolism (Agurell et al., 1984; Agurell et al., 1986). Outside of the liver, metabolism in most tissues is considerably slow or does not occur. The elimination half-life of Δ^9-THC ranges from 20 hours to between 10 and 13 days (Hunt and Jones, 1980). Lemberger et al. (1970) reported that the half-life of Δ^9-THC ranged from 23–28 hours in heavy marijuana users and up to 60 to 70 hours in naïve users. The long elimination half-life of Δ^9-THC is due to slow release of Δ^9-THC and other cannabinoids from tissues and subsequent metabolism. Inactive carboxy metabolites of Δ^9-THC have terminal half-lives of 50 hours to 6 days or more and serve as long-term markers in urine tests for marijuana use.

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[46] Available at *http://www.fda.gov/Drugs/default.htm* under Guidance (Drugs).

Most of the absorbed Δ^9-THC dose is eliminated in the feces and about 33% in urine. The glucuronide metabolite of Δ^9-THC is excreted as the major urine metabolite along with 18 non-conjugated metabolites (Agurell et al., 1986).

Research Status and Test of Currently Accepted Medical Use for Marijuana

According to the HHS, there are numerous human clinical studies with marijuana in the United States under FDA-regulated IND applications. Results of small clinical exploratory studies have been published in the medical literature. Approval of a human drug for marketing, however, is contingent upon FDA approval of a New Drug Application (NDA) or a Biologics License Application (BLA). According to the HHS, the FDA has not approved any drug product containing marijuana for marketing.

The HHS noted that a drug may be found to have a medical use in treatment in the United States for purposes of the CSA if the drug meets the five elements described by the DEA in 1992. Those five elements "are both necessary and sufficient to establish a prima facie case of currently accepted medical use" in treatment in the United States." (57 FR 10499, 10504 (March 26, 1992)). This five-element test, which the HHS and DEA have utilized in all such analyses for more than two decades, has been upheld by the Court of Appeals. *ACT,* 15 F.3d at 1135. The five elements that characterize "currently accepted medical use" for a drug are summarized here and expanded upon in the discussion below:

1. *The drug's chemistry must be known and reproducible;*
2. *There must be adequate safety studies;*
3. *There must be adequate and well-controlled studies proving efficacy;*
4. *The drug must be accepted by qualified experts; and*
5. *Scientific evidence must be widely available.*

In its review (HHS, 2015), the HHS evaluated the five elements with respect to the currently available research for marijuana. The HHS concluded that marijuana does not meet any of the five elements—all of which must be demonstrated to find that a drug has a "currently accepted medical use." A brief summary of the HHS's evaluation is provided below.

Element #1: The drug's chemistry must be known and reproducible.

"The substance's chemistry must be scientifically established to permit it to be reproduced into dosages which can be standardized. The listing of the substance in a current edition of one of the official compendia, as defined by section 201(j) of the Food, Drug and Cosmetic Act, 21 U.S.C. 321(j), is sufficient generally to meet this requirement." 57 FR 10499, 10506 (March 26, 1992).

Marijuana, as defined in the petition, includes all *Cannabis* strains. (For purposes of the CSA, marijuana includes all species of the genus *Cannabis,* including all strains therein[47]). Based on the definition of marijuana in the petition, the chemistry of marijuana is not reproducible such that a standardized dose can be created. Chemical constituents including Δ^9-THC and other cannabinoids vary significantly in marijuana samples derived from different strains (Appendino et al., 2011). As a result, there will be significant differences in safety, biological, pharmacological, and toxicological parameters amongst the various marijuana samples. Due to the variation of the chemical composition in marijuana samples, it is not possible to reproduce a standardized dose when considering all strains together. The HHS does advise that if a specific *Cannabis* strain is cultivated and processed under controlled conditions, the plant chemistry may be consistent enough to derive reproducible and standardized doses.

Element #2: There must be adequate safety studies.

"There must be adequate pharmacological and toxicological studies, done by all methods reasonably applicable, on the basis of which it could fairly and responsibly be concluded, by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, that the substance is safe for treating a specific, recognized disorder." 57 FR 10499, 10506 (March 26, 1992).

The HHS stated that there are no adequate safety studies on marijuana. As indicated in their evaluation of Element #1, the considerable variation in the chemistry of marijuana complicates the safety evaluation. The HHS concluded that marijuana does not satisfy Element #2 for having adequate safety studies such that medical and scientific experts may conclude that it is safe for treating a specific ailment.

Element #3: There must be adequate and well-controlled studies of efficacy.

"There must be adequate, well-controlled, well-designed, well-conducted and well-documented studies, including clinical investigations, by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, on the basis of which it could be fairly and responsibly concluded by such experts that the substance will have the intended effect in treating a specific, recognized disorder." 57 FR 10499, 10506 (March 26, 1992).

As indicated in the HHS's review of marijuana (HHS, 2015), there are no adequate or well-controlled studies that prove marijuana's efficacy. The FDA independently reviewed (FDA, 2015) publicly available clinical studies on marijuana published prior to February 2013 to determine if there were appropriate studies to determine marijuana's efficacy (please refer to FDA, 2015 and HHS, 2015 for more details). After review, the FDA determined that out of the identified articles, including those identified through a search of bibliographic references and 566 abstracts located on PubMed, 11 studies met the *a priori* selection criteria, including placebo control and double-blinding. FDA and HHS critically reviewed each of the 11 studies to determine if the studies met accepted scientific standards. FDA and HHS concluded that these studies do not "currently prove efficacy of marijuana" for any therapeutic indication due to limitations in the study designs. The HHS indicated that these studies could be used as proof of concept studies, providing preliminary evidence on a proposed hypothesis involving a drug's effect.

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[47] Although the CSA definition of marijuana refers only to the species "*Cannabis sativa L.,*" federal courts have consistently ruled that all species of the genus cannabis are included in this definition. *See United States* v. *Kelly,* 527 F.2d 961, 963–964 (9th Cir. 1976) (collecting and examining cases). The Single Convention (article 1, par. 1(c)) likewise defines the "cannabis plant" to mean "any plant of the genus Cannabis." As explained above in the attachment titled "Preliminary Note Regarding Treaty Considerations," 21 U.S.C. 811(d)(1) provides that, where a drug is subject to control under the Single Convention, the DEA Administrator must control the drug under the schedule he deems most appropriate to carry out such treaty obligations, without regard to the findings required by 21 U.S.C. 811(a) or 812(b) and without regard to the procedures prescribed by 21 U.S.C. 811(a) and (b).

Element #4: The drug must be accepted by qualified experts.

"[A] consensus of the national community of experts, qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, accepts the safety and effectiveness of the substance for use in treating a specific, recognized disorder. A material conflict of opinion among experts precludes a finding of consensus." 57 FR 10499, 10506 (March 26, 1992).

The HHS concluded that there is currently no evidence of a consensus among qualified experts that marijuana is safe and effective in treating a specific and recognized disorder. The HHS indicated that medical practitioners who are not experts in evaluating drugs cannot be considered qualified experts (HHS, 2015; 57 FR 10499, 10505). Further, the HHS noted that the 2009 American Medical Association (AMA) report entitled, "Use of Cannabis for Medicinal Purposes" does not conclude that there is a currently accepted medical use for marijuana. HHS also pointed out that state-level "medical marijuana" laws do not provide evidence of such a consensus among qualified experts.

Element #5: The scientific evidence must be widely available.

"In the absence of NDA approval, information concerning the chemistry, pharmacology, toxicology, and effectiveness of the substance must be reported, published, or otherwise widely available, in sufficient detail to permit experts, qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, to fairly and responsibly conclude the substance is safe and effective for use in treating a specific, recognized disorder." 57 FR 10499, 10506 (March 26, 1992).

The HHS concluded that the currently available data and information on marijuana is not sufficient to allow scientific scrutiny of the chemistry, pharmacology, toxicology, and effectiveness. In particular, scientific evidence demonstrating the chemistry of a specific *Cannabis* strain that could provide standardized and reproducible doses is not available.

Petitioners' Major Comments in Relation to Factor 3 and the Government's Responses

(1) The petitioners indicate that there is medical support and acceptance for the medical use of marijuana and stated that "*[c]annabis has been accepted by the medical community as meeting the current, modern accepted standards for what constitutes medicine.*" (Exhibit B, page 13). On page 3 of the cover letter of the petition, the petitioners stated, "*The American medical community supports rescheduling, and there are safe pharmacy-based methods to dispense medical cannabis.*"

Furthermore, they stated that "*[i]n 2009, the American Medical Association (AMA) reversed its earlier position that supported [s]chedule I classification of cannabis. The AMA now supports investigation and clinical research of cannabis for medicinal use, and urged the federal government to reassess the [s]chedule I classification. The American College of Physicians [ACP] recently expressed similar support.*" In addition, they note that the Institute of Medicine (IOM) also documented the scientific basis and therapeutic effects of cannabis (Exhibit B, page 13).

The DEA notes that the statements by the cited organizations (AMA, ACP, IOM) support more research into the potential medical properties associated with marijuana. The HHS did not find that the statements by these organizations provide evidence supporting a conclusion that adequate safety studies and adequate, well-controlled efficacy studies demonstrate the safety and efficacy of marijuana (HHS, 2015). The AMA's official policy on medicinal use of marijuana is as follows: "*Our AMA urges that marijuana's status as a federal [s]chedule I controlled substance be reviewed with the goal of facilitating the conduct of clinical research and development of cannabinoid-based medicines, and alternative delivery methods. This should not be viewed as an endorsement of state-based medical cannabis programs, the legalization of marijuana, or that scientific evidence on the therapeutic use of cannabis meets the current standards for a prescription drug product.*" (AMA, 2009).

The DEA further notes that the 2013 AMA House of Delegates report states that, "*cannabis is a dangerous drug and as such is a public health concern.*" (AMA, 2013). In 2008, the ACP indicated that "*further research is needed to compare cannabinoids' efficacy and safety with current treatments.*" (ACP, 2008). The ACP stated that, "*ACP urges an evidence-based review of marijuana's status as a [s]chedule I controlled substance to determine whether it should be reclassified to a different schedule. This review should consider the scientific findings regarding marijuana's safety and efficacy in some clinical conditions as well as evidence on the health risks associated with marijuana consumption, particularly in its crude smoked form*" (ACP, 2008). The IOM, consistent with others in the medical community, endorses further studies into the potential therapeutic uses of marijuana, but did not advocate for medicinal use without further testing (IOM, 2009).

As detailed in the HHS review, in order for a drug to be found to have a "currently accepted medical use," it must be accepted by qualified experts. There is no evidence that there is a consensus among qualified experts that marijuana is safe and effective for use in treating a specific, recognized disorder.

(2) The petitioners claim that, "*The chemistry of cannabis is known and reproducible*" (Exhibit B, page 6) and "*newer medicinal strains of cannabis are lower in THC and higher in the non-psychoactive, more therapeutic cannabinoids, such as CBD, and CBN. These compounds further improved the efficacy of cannabis.*" (Exhibit B, page 10).

As indicated by the HHS, the petitioners defined marijuana to include all *Cannabis* strains. As such, the chemistry of marijuana is not reproducible such that a standardized dose can be created. Chemical constituents including Δ^9-THC and other cannabinoids vary significantly in different marijuana samples (Appendino et al., 2011). Furthermore, the HHS cited a published report that indicates that new substances in marijuana are continually being characterized (Pollastro et al., 2011). If there is significant variance in the chemical composition of marijuana between samples, it is not possible for the chemistry to be reproducible.

Because the petition defines marijuana as including all cultivated strains, the DEA believes that the THC and CBD level of specific strains is not relevant to this consideration. In fact, the average Δ^9-THC content in marijuana has steadily risen from 1995 to 2014 as reported by the University of Mississippi Potency Monitoring Project, as presented in Factor 1. In 1995, the Δ^9-THC content was 4% on average and by 2015, the average content of THC had risen to 11.2% over a 20 year period. In the same time period, CBD and CBN percentages have ranged from 0.15% to 0.60% on average.

The DEA also notes statements in the petitioners' document that support the conclusion reached by DEA and HHS that the chemistry of marijuana as broadly defined by the petitioners is not reproducible or well-defined. For example, the petitioners acknowledge that "Cannabis is a complex plant, with several subtypes of cannabis." (Exhibit

B, page 6). The petitioners also acknowledge that "the ratios of the various cannabinoids differ according to the plant strain, and, to some extent, how the plant is grown." (Exhibit B, page 12).

(3) The petitioners stated in Exhibit B, page 8, that "*[o]verall, the 33 completed and published American controlled clinical trials with cannabis have studied its safety, routes of administration, and use in comparison with placebos, standard drugs, and in some cases dronabinol . . . ,*" and further cited a systematic review by Wang et al. (2008), that evaluated 23 randomized controlled trials and 8 observational studies, stating that, "*[o]f all the adverse events reported, 97 percent were considered 'not serious,' with the most commonly reported 'dizziness.'*"

The petitioners also cited in Exhibit B, page 8, "*There has been a long-term, prospective, federally funded cannabis clinical study jointly administered by National Institute on Drug Abuse (NIDA) and FDA. This study has been running for over 30 years without any demonstrable adverse outcomes related to chronic medicinal cannabis use.*"

As cited in the HHS recommendation document (HHS, 2015), the FDA conducted its own evaluation of the published clinical studies on the medical application of marijuana prior to February 2013 (FDA, 2015). Further details on the FDA review can be found in the published report (FDA, 2015). Based on the analysis, 11 studies were evaluated further and the FDA concluded that none of these studies "meet the criteria required by the FDA to determine if marijuana is safe and effective in specific therapeutic areas." (page 6; FDA, 2015).

The DEA has reviewed the systematic review by Wang et al. (2008) and notes that most of the studies included in the review were synthetic cannabinoid medicines (*e.g.* dronabinol) or cannabinoid extracts (*e.g.* Sativex®); these types of studies were excluded in the FDA review as the analysis focused solely on natural forms of marijuana (FDA, 2015). Wang et al. (2008) concluded that "good safety and efficacy data on smoked cannabis are urgently needed."

With respect to the 30-year study cited by the petitioners (Russo et al., 2001) on page 8 of Exhibit B, it should be clarified that the referenced study was not jointly administered by NIDA and the FDA. As with other clinical studies, an IND application was approved by the FDA and marijuana was supplied by NIDA. The authors evaluated only 8 patients over this period, of which one patient died. While the findings cited by the petitioners and authors (*e.g.* no adverse outcomes with long term marijuana use) are informative, conclusions on long-term use of marijuana cannot be applied to the general population.

Factor 4: Its History and Current Pattern of Abuse

Marijuana continues to be the most widely used illicit drug. In 2013, an estimated 24.6 million Americans age 12 or older were current (past month) illicit drug users. Of those, 19.8 million were current (past month) marijuana users. As of 2013, an estimated 114.7 million Americans age 12 and older had used marijuana or hashish in their lifetime and 33.0 million had used it in the past year.

According to the NSDUH estimates, 3.0 million people age 12 or older used an illicit drug for the first time in 2014. Marijuana initiates totaled 2.6 million in 2014. Nearly half (46.8%) of the 2.6 million new users were less than 18 years of age. In 2014, marijuana was used by 82.2% of current (past month) illicit drug users. In 2014, among past year marijuana users age 12 or older, 18.5% used marijuana on 300 or more days within the previous 12 months. This translates into 6.5 million people using marijuana on a daily or almost daily basis over a 12-month period, a significant increase from the 3.1 million daily or almost daily users in 2006 and from the 5.7 million in just the previous year. In 2014, among past month marijuana users, 41.6% (9.2 million people) used the drug on 20 or more days in the past month, a significant increase from the 8.1 million in 2013.

Marijuana is also the illicit drug with the highest numbers of past year dependence or abuse in the U.S. population. According to the 2014 NSDUH report, of the 7.1 million persons aged 12 or older who were classified with illicit drug dependence or abuse, 4.2 million of them abused or were dependent on marijuana (representing 59.0% of all those classified with illicit drug dependence or abuse and 1.6% of the total U.S. non-institutionalized population aged 12 or older).

According to the 2015 Monitoring the Future (MTF) survey, marijuana is used by a large percentage of American youths, and is the most commonly used illicit drug among American youth. Among students surveyed in 2015, 15.5% of 8th graders, 31.1% of 10th graders, and 44.7% of 12th graders reported that they had used marijuana in their lifetime. In addition, 11.8%, 25.4%, and 34.9% of 8th, 10th, and 12th graders, respectively, reported using marijuana in the past year. A number of high school students reported daily use in the past month, including 1.1%, 3.0%, and 6.0% of 8th, 10th, and 12th graders, respectively.

The prevalence of marijuana use and abuse is also indicated by criminal investigations for which drug evidence was analyzed in federal, state, and local forensic laboratories, as discussed above in Factor 1. The National Forensic Laboratory System (NFLIS), a DEA program, systematically collects drug identification results and associated information from drug cases submitted to and analyzed by federal, state, and local forensic laboratories. NFLIS data shows that marijuana was the most frequently identified drug from January 2001 through December 2014. In 2014, marijuana accounted for 29.3% (432,989) of all drug exhibits in NFLIS.

The high consumption of marijuana is being fueled by increasing amounts of domestically grown marijuana as well as increased amounts of foreign source marijuana being illicitly smuggled into the United States. In 2014, the Domestic Cannabis Eradication and Suppression Program (DCE/SP) reported that 3,904,213 plants were eradicated in outdoor cannabis cultivation areas compared to 2,597,798 in 2000, as shown above in Table 3. Significant quantities of marijuana were also eradicated from indoor cultivation operations. There were 396,620 indoor plants eradicated in 2014 compared to 217,105 eradicated in 2000. As shown in Table 2 above, in 2014, the National Seizure System (NSS) reported seizures of 1,767,741 kg of marijuana.

Petitioners' Major Comments in Relation to Factor 4 and the Government's Responses

(1) The petitioners indicated that the history and current pattern of abuse is difficult to estimate since "*a large percentage of United States citizens*" have used marijuana at least once in their lifetime and some estimates have indicated that "*over 40 percent of the nation has tried the plant.*" Further, the petitioners stated that "*trying marijuana once should not be confused with a health problem, let alone a diagnosis of dependence or abuse.*" (Exhibit B, page 26).

Marijuana usage numbers mentioned in both the HHS Recommendation and this DEA document include surveys from NSDUH and MTF. These surveys measure extent of use of marijuana. As mentioned in this Factor, according to the results of the 2013 NSDUH survey, 17.4% of past year marijuana users age 12 or older used marijuana on 300 or more days within the previous 12 months. This indicates that 5.7 million people used marijuana on a daily or almost daily basis over this 12-month period, which is a 1.8-fold increase from the 3.1 million daily or almost daily users in 2006. Furthermore, 6% of all twelfth graders in the United States reported daily use of marijuana in the 2015 MTF survey. These data strongly indicate that there is a significant portion of the U.S. population using marijuana on a daily basis.

(2) As stated in Exhibit B on page 26, subpart A, "*Rates of dependence or abuse are remarkably low*" and further suggest that "*[i]nterviews for the National Longitudinal Alcohol Epidemiological Survey ([NLAES]* [sic] *and National Epidemiological Survey on Alcohol and Related Conditions ([NESARC]* [sic] *each confirm that rates of dependence or abuse of cannabis have never exceed (sic) two percent in a given year.*"

The authors of study cited by the petitioners (Compton et al., 2004) concluded that a higher percentage of American adults had a marijuana use disorder in 2001–2002 (1.5%) than in 1991–1992 (1.2%). Compton et al. (2004) noted that the marijuana use disorder increase of 0.3% over the 10 year period would equate to an increase from 2.2 million people to 3 million people in the United States. The petitioners failed to explain the impact of 1.5% (or less than 2 percent) of the U.S. population having a marijuana use disorder. In order to put these numbers into perspective, the DEA reviewed the literature and found that non-medical prescription drug use and abuse rates were examined in the same NLAES and NESARC (1991–1992 and 2001–2002) populations (Blanco et al., 2007). Blanco et al (2007) examined non-medical prescription drug use and abuse rates from the periods of 1991–1992 and 2001–2002. In 1991 through 1992, the prevalence of non-medical prescription drug (opioid, stimulant, and tranquilizer) abuse and dependence was 0.1%. Non-medical prescription drug (primarily opioid-based drugs) abuse and dependence increased to 0.3% in 2001 through 2002. Therefore, in the same 2001–2002 NLAES and NESARC populations, the percentage of people with a marijuana use disorder was approximately five-fold higher (1.5% versus 0.3%) than those with opioid abuse and dependence resulting from non-medical prescription drug use.

Further, Volkow et al. (2014) reported that in long-term or heavy marijuana users, 9% of users become addicted to marijuana. This percentage increases to 17% when marijuana use starts in adolescence and it increases to 25 to 50% of those who are daily users.

Factor 5: The Scope, Duration, and Significance of Abuse

Abuse of marijuana is widespread and significant. As previously noted, according to the NSDUH, in 2014, an estimated 117.2 million Americans (44.2%) age 12 or older had used marijuana or hashish in their lifetime, 35.1 million (13.2%) had used it in the past year, and 22.2 million (8.4%) had used it in the past month. Past year and past month marijuana use has increased significantly since 2013. Past month marijuana use is highest among 18–21 year olds and it declines among those 22 years of age and older. In 2014, an estimated 18.5% of past year marijuana users age 12 or older used marijuana on 300 or more days within the past 12 months. This translates into 6.5 million persons using marijuana on a daily or almost daily basis over a 12-month period. In 2014, an estimated 41.6% (9.2 million) of past month marijuana users age 12 or older used the drug on 20 or more days in the past month (SAMHSA, NSDUH). Chronic use of marijuana is associated with a number of health risks (see Factors 2 and 6).

Furthermore, the average percentage of Δ^9-THC in seized marijuana has increased over the past two decades (The University of Mississippi Potency Monitoring Project). Additional studies are needed to clarify the impact of greater potency, but one study shows that higher levels of Δ^9-THC in the body are associated with greater psychoactive effects (Harder and Rietbrock, 1997), which can be correlated with higher abuse potential (Chait and Burke, 1994).

TEDS data show that in 2013, marijuana/hashish was the primary substance of abuse in 16.8% of all admissions to substance abuse treatment among patients age 12 and older. TEDS data also show that marijuana/hashish was the primary substance of abuse for 77.0% of all 12- to 14-year-olds admitted for drug treatment and 75.5% of all 15- to 17-year-olds admitted for drug treatment in 2013. Among the 281,991 admissions to drug treatment in 2013 in which marijuana/hashish was the primary drug, the average age at admission was 25 years and the peak age cohort was 15 to 17 years (22.5%). Thirty-nine percent of the 281,991 primary marijuana/hashish admissions (35.9%) were under the age of 20.

In summary, the recent statistics from these various surveys and databases (see Factor 1 for more details) demonstrate that marijuana continues to be the most commonly used illicit drug, with large incidences of heavy use and dependence in teenagers and young adults.

Petitioners' Major Comment in Relation to Factor 5 and DEA's Response

(1) Petitioners' contend that, "*The prevalence and significance of potential abuse are limited for cannabis, especially in relation to other [s]chedule II substances.*" The petitioners cited results from the 1990 NIDA Household Survey on Drug Abuse and indicated that, "*more than four out of five people who had used cannabis in the previous year reported no problems related to the drug.*" (Exhibit B, page 28).

The prevalence of marijuana usage and marijuana dependence is significant in the United States. The 2014 NSDUH findings indicate that there are approximately 6.5 million Americans using marijuana on a daily or almost daily basis. Further, Volkow et al. (2014) reported that in long-term or heavy marijuana users, 9% of users become addicted to marijuana. Among those who began using marijuana in adolescence, marijuana dependence increases to 17%, and it further increases to 25 to 50% of daily users that started using marijuana during adolescence. These collective findings indicate that there is considerable significance associated with marijuana use and abuse since 9% of users become addicted to marijuana, 25 to 50% of daily marijuana users started during adolescence, and prevalence of usage is significantly high based on the data presented from Volkow et al (2014) and the 2014 NSDUH survey.

Factor 6: What, if any, Risk There is to the Public Health

In its recommendation, the HHS discussed public health risks associated with acute and chronic marijuana use in Factor 6. Public health risks as measured by emergency department visits and drug treatment admissions are discussed by HHS and DEA in Factors 1, 4, and 5. Similarly, Factor 2 discusses marijuana's pharmacology and presents some of the adverse health effects associated with use. Marijuana use may affect the physical and/or psychological functioning of an individual user, but may also have broader public impacts including driving impairments and fatalities from car accidents.

Risks From Acute Use of Marijuana

As discussed in the HHS review document (HHS, 2015), acute usage of marijuana impairs psychomotor performance including motor control and impulsivity, risk taking and executive function (Ramaekers et al., 2004; Ramaekers et al., 2006). In a minority of individuals using marijuana, dysphoria, prolonged anxiety, and psychological distress may be observed (Haney et al., 1999). The DEA further notes a recent review of acute marijuana effects (Wilkinson et al., 2014) that reported impaired neurological function including altered perception, paranoia, delayed response time, and memory deficits.

In its recommendation, HHS references a meta-analysis conducted by Li et al (2012) where the authors concluded that psychomotor impairments associated with acute marijuana usage have also been associated with increased risk of car accidents with individuals experiencing acute marijuana intoxication (Li et al., 2012; HHS, 2015). The DEA further notes more recent studies examining the risk associated with marijuana use and driving. Younger drivers (under 21) have been characterized as the highest risk group associated with marijuana use and driving (Whitehill et al., 2014). Furthermore, in 2013, marijuana was found in 13% of the drivers involved in automobile-related fatal accidents (McCartt, 2015). The potential risk of automobile accidents associated with marijuana use appears to be increasing since there has been a steady increase in individuals intoxicated with marijuana over the past 20 years (Wilson et al., 2014). However, a recent study commissioned by the National Highway Traffic Safety Administration (NHTSA) reported that when adjusted for confounders (*e.g.,* alcohol use, age, gender, ethnicity), there was not a significant increase in crash risk (fatal and nonfatal, n = 2,682) associated with marijuana use (Compton and Berning, 2015).

The DEA also notes recent studies examining unintentional exposures of children to marijuana (Wang et al., 2013; 2014). Wang et al. (2013) reviewed emergency department (ED) visits at a children's hospital in Colorado from January 1, 2005 to December 31, 2011. As stated by the authors, in 2000 Colorado passed Amendment 20 which allowed for the use of marijuana. Following the passage of "a new Justice Department policy" instructing "federal prosecutors not to seek arrest of medical marijuana users and suppliers as long as they conform to state laws" (as stated in Wang et al., 2013), 14 patients in Colorado under the age of 12 were admitted to the ED for the unintended use of marijuana over a 27 month period. Prior to the passage of this policy, from January 1, 2005 to September 30, 2009 (57 months), there were no pediatric ED visits due to unintentional marijuana exposure (Wang et al., 2013). The DEA also notes a larger scale evaluation of pediatric exposures using the National Poison Data System (Wang et al., 2014). That study reported that there were 985 unintentional marijuana exposures in children (9 years and younger) between January 1, 2005 to December 31, 2011. The authors stratified the ED visits by states with laws allowing medical use of marijuana, states transitioning to legalization for medical use, and states with no such laws. Out of the 985 exposures, 495 were in non-legal states (n = 33 states), 93 in transitional states (n = 8 states), and 396 in "legal" states (n = 9 states). The authors reported that there was a twofold increase (OR = 2.1) in moderate or major effects in children with unintentional marijuana use and a threefold increase (OR = 3.4) in admissions to critical care units in states allowing medical use of marijuana, in comparison to non-legal states.

Risks Associated With Chronic Use of Marijuana

The HHS noted that a major risk from chronic marijuana use is a distinctive withdrawal syndrome, as described in the 2013 DSM–5. The HHS analysis also quoted the following description of risks associated with marijuana [cannabis] abuse from the DSM–5:

> *Individuals with cannabis use disorder may use cannabis throughout the day over a period of months or years, and thus may spend many hours a day under the influence. Others may use less frequently, but their use causes recurrent problems related to family, school, work, or other important activities (e.g., repeated absences at work; neglect of family obligations). Periodic cannabis use and intoxication can negatively affect behavioral and cognitive functioning and thus interfere with optimal performance at work or school, or place the individual at increased physical risk when performing activities that could be physically hazardous (e.g. driving a car; playing certain sports; performing manual work activities, including operating machinery). Arguments with spouses or parents over the use of cannabis in the home, or its use in the presence of children, can adversely impact family functioning and are common features of those with cannabis use disorder. Last, individuals with cannabis use disorder may continue using marijuana despite knowledge of physical problems (e.g. chronic cough related to smoking) or psychological problems (e.g. excessive sedation or exacerbation of other mental health problems) associated with its use.* (HHS 2015, page 34).

The HHS stated that chronic marijuana use produces acute and chronic adverse effects on the respiratory system, memory and learning. Regular marijuana smoking can produce a number of long-term pulmonary consequences, including chronic cough and increased sputum (Adams and Martin, 1996), and histopathologic abnormalities in bronchial epithelium (Adams and Martin, 1996).

Marijuana as a "Gateway Drug"

The HHS reviewed the clinical studies evaluating the gateway hypothesis in marijuana and found them to be limited. The primary reasons were: (1) Recruited participants were influenced by social, biological, and economic factors that contribute to extensive drug abuse (Hall and Lynskey, 2005), and (2) most studies testing the gateway drug hypothesis for marijuana use the determinative measure *any use of an illicit drug* rather than applying DSM–5 criteria for drug abuse or dependence (DSM–5, 2013).

The HHS cited several studies where marijuana use did not lead to other illicit drug use (Kandel and Chen, 2000; von Sydow et al., 2002; Nace et al., 1975). Two separate longitudinal studies with adolescents using marijuana did not demonstrate an association with use of other illicit drugs (Kandel and Chen, 2000; von Sydow et al., 2002).

It was noted by the HHS that, when evaluating the gateway hypothesis, differences appear when examining use versus abuse or dependence of other illicit drugs. Van Gundy and Rebellon (2010) reported that there was a correlation between marijuana use in adolescence and other illicit drug use in early adulthood, but when examined in terms of drug abuse of other illicit drugs, age-linked stressors and social roles were confounders in the association. Degenhardt et al. (2009) reported that marijuana use often precedes use of other illicit drugs, but dependence involving drugs other than marijuana frequently correlated with higher levels of illicit drug abuse. Furthermore, Degenhardt et al. (2010) reported that in countries with lower prevalence of marijuana usage, use of other illicit drugs before marijuana was often documented.

Based on these studies among others, the HHS concluded that although many individuals with a drug abuse disorder may have used marijuana as one of their first illicit drugs, this does not mean that individuals initiated with marijuana inherently will go on to become regular users of other illicit drugs.

Petitioners' Major Comment in Relation to Factor 6 and the Government's Responses

(1) The petitioners commented that marijuana does not significantly impact social behavior in domains such as motivation, driving, aggression, or hostility (Exhibit B, pages 30–41).

The HHS concluded that "Marijuana's acute effects can significantly interfere with a person's ability . . . to operate motor vehicles." (HHS, 2015) As mentioned in this factor, there is a significant risk with marijuana use and driving. Marijuana was found in 13% of drivers involved in automobile fatal accidents (McCartt, 2015). Furthermore, in a meta-analysis conducted by Li et al. (2011), an association was identified between marijuana use by the driver and an increased risk of getting into a car accident.

The DEA notes that the petitioners only considered whether marijuana creates social problems, and did not consider physiological changes and impacts that also should be evaluated in determining the risk to public health. The HHS and DEA considered the public health impacts of such physiological effects, as discussed in this factor and others above. Marijuana may result in acute cardiovascular toxicity as indicated by recent reviews examining these associations (Hackham, 2015; Panayiotides, 2015). There is a possible association between frequent, long-term marijuana use and increased risk of testicular germ cell cancers and some evidence that chronic marijuana use may lead to lung cancer although the evidence is inconsistent. Furthermore, a more recent risk is the increase in ED visits of children unintentionally exposed to marijuana with increased risk factors for major adverse effects or admission to critical care units in states that have legalized marijuana for medical purposes (Wang et al., 2014).

Factor 7: Its Psychic or Physiological Dependence Liability

Physiological (Physical) Dependence in Humans

The HHS stated that heavy and chronic use of marijuana can lead to physical dependence (DSM–5, 2013; Budney and Hughes, 2006; Haney et al., 1999). Tolerance is developed following repeated administration of marijuana and withdrawal symptoms are observed as following discontinuation of marijuana usage (HHS, 2015).

The HHS mentioned that tolerance can develop to some of marijuana's effects, but does not appear to develop with respect to the psychoactive effects. It is believed that lack of tolerance to psychoactive effects may relate to electrophysiological data demonstrating that chronic Δ^9-THC administration does not affect increased neuronal firing in the ventral tegmental area, a brain region that plays a critical role in drug reinforcement and reward (Wu and French, 2000). Humans can develop tolerance to marijuana's cardiovascular, autonomic, and behavioral effects (Jones et al., 1981). Tolerance to some behavioral effects appears to develop with heavy and chronic use, but not with occasional usage. Ramaekers et al. (2009) reported that following acute administration of marijuana, occasional marijuana users still exhibited impairments in tracking and attention tasks whereas performance of heavy users on the these tasks was not affected. In a follow-up study with the same subjects that participated in the study by Ramaekers et al. (2009), a neurophysiological assessment was conducted where event-related potentials (ERPs) were measured using electroencephalography (EEG) (Theunissen et al., 2012). Similar to the earlier results, the heavy marijuana users (n = 11; average of 340 marijuana uses per year) had no changes in their ERPs with the acute marijuana exposure. However, occasional users (n = 10; average of 55 marijuana uses per year) had significant decreases in the amplitude of an ERP component (categorized as P100) on tracking and attention tasks and ERP amplitude change is indicative of a change in brain activity (Theunissen et al., 2012).

The HHS indicated that down-regulation of cannabinoid receptors may be a possible mechanism for tolerance to marijuana's effects (Hirvonen et al., 2012; Gonzalez et al., 2005; Rodriguez de Fonseca et al., 1994; Oviedo et al., 1993).

As indicated by the HHS, the most common withdrawal symptoms in heavy, chronic marijuana users are sleep difficulties, decreased appetite or weight loss, irritability, anger, anxiety or nervousness, and restlessness (Budney and Hughes, 2006; Haney et al., 1999). As reported by HHS, most marijuana withdrawal symptoms begin within 24–48 hours of discontinuation, peak within 4–6 days, and last for 1–3 weeks.

The HHS pointed out that the American Psychiatric Association's (APA's) Diagnostic and Statistical Manual of Mental Disorders-5 (DSM–5) included a list of withdrawal symptoms following marijuana [cannabis] use (DSM–5, 2013). The DEA notes that a DSM–5 working group report indicated that marijuana withdrawal symptoms were added to DSM–5 (they were not previously included in DSM–IV) because marijuana withdrawal has now been reliably presented in several studies (Hasin et al., 2013). In short, marijuana withdrawal signs are reported in up to one-third of regular users and between 50% and 90% of heavy users (Hasin et al., 2013). According to DSM–5 criteria, in order to be characterized as having marijuana withdrawal, an individual must develop at least three of the seven symptoms within one week of decreasing or stopping the heavy and prolonged use (DSM–5, 2013). These seven symptoms are: (1) Irritability; anger or aggression, (2) nervousness or anxiety, (3) sleep difficulty, (4) decreased appetite or weight loss, (5) restlessness, (6) decreased mood, (7) somatic symptoms causing significant discomfort (DSM–5, 2013).

Psychological (Psychic) Dependence in Humans

High levels of psychoactive effects such as positive reinforcement correlate with increased marijuana abuse and dependence (Scherrer et al., 2009; Zeiger et al., 2010). Epidemiological marijuana use data reported by NSDUH, MTF, and TEDS support this assertion as presented in the HHS 2015 review of marijuana and updated by the DEA. According to the findings in the 2014 NSDUH survey, an estimated 9.2 million individuals 12 years and older used marijuana daily or almost daily (20 or more days within the past month). In the 2015 MTF report, daily marijuana use (20 or more days within the past 30 days) in 8th, 10th, and 12th graders is 1.1%, 3.0%, and 6.0%, respectively.

The 2014 NSDUH report stated that 4.2 million persons were classified with dependence on or abuse of marijuana in the past year (representing 1.6% of the total population age 12 or older, and 59.0% of those classified with illicit drug dependence or abuse) based on criteria specified in the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM–IV). Furthermore, of the admissions to licensed substance abuse facilities, as presented in TEDS, marijuana/hashish was the primary substance of abuse for; 18.3% (352,297) of 2011 admissions; 17.5% (315,200) of 2012 admissions; and 16.8% (281,991) of 2013 admissions. Of the 281,991 admissions in 2013 for marijuana/hashish as the primary substance, 24.3% used marijuana/hashish daily. Among admissions to treatment for marijuana/hashish as the primary substance in 2013, 27.4% were ages 12 to 17 years and 29.7% were ages 20 to 24 years.

Petitioners' Major Comment in Relation to Factor 7 and the Government's Response

(1) The petitioners stated, *"There is no severe physical withdrawal syndrome associated with cannabis. Cannabis addiction is amenable to treatment."* (Exhibit B, page 10). The petitioners further indicated that marijuana *"may be psychologically addictive, but much less so than other Scheduled* [sic] *II drugs,"* (Exhibit B, page 10) and that there is a low risk of dependence associated with marijuana use. Petitioners further stated in Exhibit B, page 23, *"Cannabis has low relative dependence risk and does not reach the severity associated with other drugs."*

The HHS states that marijuana withdrawal syndrome "appears to be mild compared to classical alcohol and barbiturate withdrawal syndromes" and is similar in magnitude and time course to tobacco withdrawal syndrome.

DSM–5 now recognizes and describes a marijuana [cannabis] withdrawal syndrome. The lifetime risk of dependence to marijuana is approximately 9% among heavy or long-term users (Volkow et al., 2014). Marijuana results in tolerance and withdrawal as described earlier in this Factor 7. The data from NSDUH indicate that there is constant desire for marijuana as noted by the consistently high numbers of current daily users in adults and adolescents. Marijuana use also persists despite problems associated with the drug. Changes in IQ have been noted in adolescent-onset, chronic or dependent marijuana users, in addition to withdrawal symptoms. However, marijuana use has not declined in the time that usage of this drug has been monitored. Additionally, there has been an increase in content of the primary psychoactive chemical, Δ^9-THC, in marijuana samples analyzed by the University of Mississippi's Potency Monitoring Project, suggesting preference for marijuana strains with higher levels of Δ^9-THC.

Factor 8: Whether the Substance is an Immediate Precursor of a Substance Already Controlled Under the CSA

Marijuana is not an immediate precursor of another controlled substance.

Determination

After consideration of the eight factors discussed above and of the HHS's Recommendation, the DEA finds that marijuana meets the three criteria for placing a substance in schedule I of the CSA under 21 U.S.C. 812(b)(1):

1. Marijuana has a high potential for abuse.

The HHS concluded that marijuana has a high potential for abuse based on a large number of people regularly using marijuana, its widespread use, and the vast amount of marijuana that is available through illicit channels.

Marijuana is the most abused and trafficked illicit substance in the United States. Approximately 22.2 million individuals in the United States (8.4% of the United States population) were past month users of marijuana according to the 2014 NSDUH survey. A 2015 national survey (Monitoring the Future) that tracks drug use trends among high school students showed that by 12th grade, 21.3% of students reported using marijuana in the past month, and 6.0% reported having used it daily in the past month. In 2011, SAMHSA's Drug Abuse Warning Network (DAWN) reported that marijuana was mentioned in 36.4% of illicit drug-related emergency department (ED) visits, corresponding to 455,668 out of approximately 1.25 million visits. The Treatment Episode Data Set (TEDS) showed that 16.8% of non-private substance-abuse treatment facility admissions in 2013 were for marijuana as the primary drug.

Marijuana has dose-dependent reinforcing effects that encourage its abuse. Both clinical and preclinical studies have demonstrated that marijuana and its principle psychoactive constituent, Δ^9-THC, possess the pharmacological attributes associated with drugs of abuse. They function as discriminative stimuli and as positive reinforcers to maintain drug use and drug-seeking behavior. Additionally, use of marijuana can result in psychological dependence.

2. Marijuana has no currently accepted medical use in treatment in the United States.

The HHS stated that the FDA has not approved an NDA for marijuana. The HHS noted that there are opportunities for scientists to conduct clinical research with marijuana and there are active INDs for marijuana, but marijuana does not have a currently accepted medical use in the United States, nor does it have an accepted medical use with severe restrictions.

FDA approval of an NDA is not the sole means through which a drug can be determined to have a "currently accepted medical use" under the CSA. Applying the five-part test summarized below, a drug has a currently accepted medical use if all of the following five elements have been satisfied. As detailed in the HHS evaluation and as set forth below, none of these elements has been fulfilled for marijuana:

i. *The drug's chemistry must be known and reproducible.*

Chemical constituents including Δ^9-THC and other cannabinoids in marijuana vary significantly in different marijuana strains. In addition, the concentration of Δ^9-THC and other cannabinoids may vary between strains. Therefore the chemical composition among different marijuana samples is not reproducible. Due to the variation of the chemical composition in marijuana strains, it is not possible to derive a standardized dose. The HHS does advise that if a specific *Cannabis* strain is cultivated and processed under controlled conditions, the plant chemistry may be consistent enough to derive standardized doses.

ii. *There must be adequate safety studies.*

There are not adequate safety studies on marijuana for use in any specific, recognized medical condition. The considerable variation in the chemistry of marijuana results in differences in safety, biological, pharmacological, and toxicological parameters amongst the various marijuana samples.

iii. *There must be adequate and well-controlled studies proving efficacy.*

There are no adequate and well-controlled studies that determine marijuana's efficacy. In an independent review performed by the FDA of publicly available clinical studies on marijuana (FDA, 2015), FDA concluded that these studies do not have enough information to "*currently prove efficacy of marijuana*" for any therapeutic indication.

iv. *The drug must be accepted by qualified experts.*

At this time, there is no consensus of opinion among experts concerning the medical utility of marijuana for use in treating specific recognized disorders.

v. *The scientific evidence must be widely available.*

The currently available data and information on marijuana is not sufficient to address the chemistry, pharmacology, toxicology, and effectiveness. The scientific evidence regarding marijuana's chemistry with regard to a specific cannabis strain that could be formulated into standardized and reproducible doses is not currently available.

3. There is a lack of accepted safety for use of marijuana under medical supervision.

Currently, there are no FDA-approved marijuana products. The HHS also concluded that marijuana does not have a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions. According to the HHS, the FDA is unable to conclude that marijuana has an acceptable level of safety in relation to its effectiveness in treating a specific and recognized disorder due to lack of evidence with respect to a consistent and reproducible dose that is contamination free. The HHS indicated that marijuana research investigating potential medical use should include information on the chemistry, manufacturing, and specifications of marijuana. The HHS further indicated that a procedure for delivering a consistent dose of marijuana should also be developed. Therefore, the HHS concluded that marijuana does not have an acceptable level of safety for use under medical supervision.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Chapter II

[Docket No. DEA–427]

Denial of Petition To Initiate Proceedings To Reschedule Marijuana

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Denial of petition to initiate proceedings to reschedule marijuana.

SUMMARY: By letter dated July 19, 2016 the Drug Enforcement Administration (DEA) denied a petition to initiate rulemaking proceedings to reschedule marijuana. Because the DEA believes that this matter is of particular interest to members of the public, the agency is publishing below the letter sent to the petitioner which denied the petition, along with the supporting documentation that was attached to the letter.

DATES: August 12, 2016.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812

SUPPLEMENTARY INFORMATION:

July 19, 2016

Dear Mr. Krumm:

On December 17, 2009, you petitioned the Drug Enforcement Administration (DEA) to initiate rulemaking proceedings under the rescheduling provisions of the Controlled Substances Act (CSA). Specifically, you petitioned DEA to have marijuana removed from schedule I of the CSA and rescheduled in any schedule other than schedule I of the CSA.

You requested that DEA remove marijuana from schedule I based on your assertion that:

1. Marijuana has accepted medical use in the United States;
2. Studies have shown that smoked marijuana has proven safety and efficacy;
3. Marijuana is safe for use under medical supervision; and
4. Marijuana does not have the abuse potential for placement in schedule I

In accordance with the CSA scheduling provisions, after gathering the necessary data, DEA requested a scientific and medical evaluation and scheduling recommendation from the Department of Health and Human Services (HHS). HHS concluded that marijuana has a high potential for abuse, has no accepted medical use in the United States, and lacks an acceptable level of safety for use even under medical supervision. Therefore, HHS recommended that marijuana remain in schedule I. The scientific and medical evaluation and scheduling recommendation that HHS submitted to DEA is attached hereto.

Based on the HHS evaluation and all other relevant data, DEA has concluded that there is no substantial evidence that marijuana should be removed from schedule I. A document prepared by DEA addressing these materials in detail also is attached hereto. In short, marijuana continues to meet the criteria for schedule I control under the CSA because:

(1) *Marijuana has a high potential for abuse.* The HHS evaluation and the additional data gathered by DEA show that marijuana has a high potential for abuse.

(2) *Marijuana has no currently accepted medical use in treatment in the United States.* Based on the established five-part test for making such determination, marijuana has no "currently accepted medical use" because: As detailed in the HHS evaluation, the drug's chemistry is not known and reproducible; there are no adequate safety studies; there are no adequate and well-controlled studies proving efficacy; the drug is not accepted by qualified experts; and the scientific evidence is not widely available.

(3) *Marijuana lacks accepted safety for use under medical supervision.* At present, there are no U.S. Food and Drug Administration (FDA)-approved marijuana products, nor is marijuana under a New Drug Application (NDA) evaluation at the FDA for any indication. The HHS evaluation states that marijuana does not have a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions. At this time, the known risks of marijuana use have not been shown to be outweighed by specific benefits in well-controlled clinical trials that scientifically evaluate safety and efficacy.

The statutory mandate of 21 U.S.C. 812(b) is dispositive. Congress established only one schedule, schedule I, for drugs of abuse with "no currently accepted medical use in treatment in the United States" and "lack of accepted safety for use under medical supervision." 21 U.S.C. 812(b).

Although the HHS evaluation and all other relevant data lead to the conclusion that marijuana must remain in schedule I, it should also be noted that, in view of United States obligations under international drug control treaties, marijuana cannot be placed in a schedule less restrictive than schedule II. This is explained in detail in the accompanying document titled "Preliminary Note Regarding Treaty Considerations."

Accordingly, and as set forth in detail in the accompanying HHS and DEA documents, there is no statutory basis under the CSA for DEA to grant your petition to initiate rulemaking proceedings to reschedule marijuana. Your petition is, therefore, hereby denied.

Sincerely,

Chuck Rosenberg,

Acting Administrator

Attachments:

Preliminary Note Regarding Treaty Considerations

Cover Letter from HHS to DEA Summarizing the Scientific and Medical Evaluation and Scheduling Recommendation for Marijuana.

U.S. Department of Health and Human Services (HHS)—Basis for the Recommendation for Maintaining Marijuana in Schedule I of the Controlled Substances Act

U.S. Department of Justice—Drug Enforcement Administration (DEA), Schedule of Controlled Substances: Maintaining Marijuana in Schedule I of the Controlled Substances Act, Background, Data, and Analysis: Eight Factors Determinative of Control and Findings Pursuant to 21 U.S.C. 812(b)

Dated: July 19, 2016.

Chuck Rosenberg,

Acting Administrator.

Preliminary Note Regarding Treaty Considerations

As the Controlled Substances Act (CSA) recognizes, the United States is a party to the Single Convention on Narcotic Drugs, 1961 (referred to here as the Single Convention or the treaty). 21 U.S.C. 801(7). Parties to the Single Convention are obligated to maintain various control provisions related to the drugs that are covered by the treaty. Many of the provisions of the CSA were enacted by Congress for the specific purpose of ensuring U.S. compliance with the treaty. Among these is a scheduling provision, 21 U.S.C. 811(d)(1). Section 811(d)(1) provides that, where a drug is subject to control under the Single Convention, the DEA Administrator (by delegation from the Attorney General) must "issue an order controlling such drug under the schedule he deems most appropriate to carry out such [treaty] obligations, without regard to the findings required by [21 U.S.C. 811(a) or 812(b)] and without regard to the procedures prescribed by [21 U.S.C. 811(a) and (b)]."

Marijuana is a drug listed in the Single Convention. The Single Convention uses the term "cannabis" to refer to marijuana.[1] Thus, the DEA Administrator is obligated under section 811(d) to control marijuana in the schedule that he deems most appropriate to carry out the U.S. obligations under the Single Convention. It has been established in prior marijuana rescheduling proceedings that placement of marijuana in either schedule I or schedule II of the CSA is "necessary as well as sufficient to satisfy our international obligations" under the Single Convention. *NORML* v. *DEA,* 559 F.2d 735, 751 (D.C. Cir. 1977). As the United States Court of Appeals for the D.C. Circuit has stated, "several requirements imposed by the Single Convention would not be met if cannabis and cannabis resin were placed in CSA schedule III, IV, or V."[2] *Id.* Therefore, in accordance with section 811(d)(1), DEA must place marijuana in either schedule I or schedule II.

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[1] Under the Single Convention, "'cannabis plant' means any plant of the genus Cannabis." Article 1(c). The Single Convention defines "cannabis" to include "the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated." Article 1(b). This definition of "cannabis" under the Single Convention is slightly less inclusive than the CSA definition of "marihuana," which includes all parts of the cannabis plant except for the mature stalks, sterilized seeds, oil from the seeds, and certain derivatives thereof. *See* 21 U.S.C. 802(16). Cannabis and cannabis resin are included in the list of drugs in Schedule I and Schedule IV of the Single Convention. In contrast to the CSA, the drugs listed in Schedule IV of the Single Convention are also listed in Schedule I of the Single Convention and are subject to the same controls as Schedule I drugs as well as additional controls. Article 2, par. 5

Because schedules I and II are the only possible schedules in which marijuana may be placed, for purposes of evaluating this scheduling petition, it is essential to understand the differences between the criteria for placement of a substance in schedule I and those for placement in schedule II. These criteria are set forth in 21 U.S.C. 812(b)(1) and (b)(2), respectively. As indicated therein, substances in both schedule I and schedule II share the characteristic of "a high potential for abuse." Where the distinction lies is that schedule I drugs have "no currently accepted medical use in treatment in the United States" and "a lack of accepted safety for use of the drug . . . under medical supervision," while schedule II drugs do have "a currently accepted medical use in treatment in the United States."[3]

Accordingly, in view of section 811(d)(1), this scheduling petition turns on whether marijuana has a currently accepted medical use in treatment in the United States. If it does not, DEA must, pursuant to section 811(d), deny the petition and keep marijuana in schedule I.

As indicated, where section 811(d)(1) applies to a drug that is the subject of a rescheduling petition, the DEA Administrator must issue an order controlling the drug under the schedule he deems most appropriate to carry out United States obligations under the Single Convention, without regard to the findings required by sections 811(a) or 812(b) and without regard to the procedures prescribed by sections 811(a) and (b). Thus, since the only determinative issue in evaluating the present scheduling petition is whether marijuana has a currently accepted medical use in treatment in the United States, DEA need not consider the findings of sections 811(a) or 812(b) that have no bearing on that determination, and DEA likewise need not follow the procedures prescribed by sections 811(a) and (b) with respect to such irrelevant findings. Specifically, DEA need not evaluate the relative abuse potential of marijuana or the relative extent to which abuse of marijuana may lead to physical or psychological dependence.

As explained below, the medical and scientific evaluation and scheduling recommendation issued by the Secretary of Health and Human Services concludes that marijuana has no currently accepted medical use in treatment in the United States, and the DEA Administrator likewise so concludes. For the reasons just indicated, no further analysis beyond this consideration is required. Nonetheless, because of the widespread public interest in understanding all the facts relating to the harms associated with marijuana, DEA is publishing here the entire medical and scientific analysis and scheduling evaluation issued by the Secretary, as well as DEA's additional analysis.

Department of Health and Human Services, Office of the Secretary Assistant Secretary for Health, Office of Public Health and Science
Washington DC 20201.

June 25, 2015.

The Honorable Chuck Rosenberg
Acting Administrator, Drug Enforcement Administration, U.S. Department of Justice, 8701 Morrissette Drive, Springfield, VA 22152

Dear Mr. Rosenberg:

Pursuant to the Controlled Substances Act (CSA, 21 U.S.C. 811(b), (c), and (f)), the Department of Health and Human Services (HHS) is recommending that marijuana continue to be maintained in Schedule I of the CSA.

The Food and Drug Administration (FDA) has considered the abuse potential and dependence-producing characteristics of marijuana.

Marijuana meets the three criteria for placing a substance in Schedule I of the CSA under 21 U.S.C. 812(b)(1). As discussed in the enclosed analyses, marijuana has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Accordingly, HHS recommends that marijuana be maintained in Schedule I of the CSA. Enclosed are two documents prepared by FDA's Controlled Substance Staff (in response to petitions filed in 2009 by Mr. Bryan Krumm and in 2011 by Governors Lincoln D. Chafee and Christine O. Gregoire) that form the basis for the recommendation. Pursuant to the requests in the petitions, FDA broadly evaluated marijuana, and did not focus its evaluation on particular strains of marijuana or components or derivatives of marijuana.

FDA's Center for Drug Evaluation and Research's current review of the available evidence and the published clinical studies on marijuana demonstrated that since our 2006 scientific and medical evaluation and scheduling recommendation responding to a previous DEA petition, research with marijuana has progressed. However, the available evidence is not sufficient to determine that marijuana has an accepted medical use. Therefore, more research is needed into marijuana's effects, including potential medical uses for marijuana and its derivatives. Based on the current review, we identified several methodological challenges in the marijuana studies published in the literature. We recommend they be addressed in future clinical studies with marijuana to ensure that valid scientific data are generated in studies evaluating marijuana's safety and efficacy for therapeutic use. For example, we recommend that studies need to focus on consistent administration and reproducible dosing of marijuana, potentially through the use of administration methods other than smoking. A summary of our review of the published literature on the clinical uses of marijuana, including recommendations for future studies, is attached to this document.

FDA and the National Institutes of Health's National Institute on Drug Abuse (NIDA) also believe that work continues to be needed to ensure support by the federal government for the efficient conduct of clinical research using marijuana. Concerns have been raised about whether the existing federal regulatory system is flexible enough to respond to increased interest in research into the potential therapeutic uses of marijuana and marijuana-derived drugs. HHS welcomes an opportunity to continue to explore these concerns with DEA.

Should you have any questions regarding theses recommendations, please contact Corinne P. Moody, Science Policy Analyst, Controlled Substances Staff, Center for Drug Evaluation and Research, FDA, at (301) 796–3152.

Sincerely yours,

Karen B. DeSalvo, MD, MPH, MSc
Acting Assistant Secretary for Health

Enclosure:

Basis for the Recommendation for Maintaining Marijuana in Schedule I of the Controlled Substances Act

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[2] The Court further stated: "For example, [article 31 paragraph 4 of the Single Convention] requires import and export permits that would not be obtained if the substances were placed in CSA schedules III through V. In addition, the quota and [recordkeeping] requirements of Articles 19 through 21 of the Single Convention would be satisfied only by placing the substances in CSA schedule I or II." *Id.* n. 71 (internal citations omitted).

[3] As DEA has stated in evaluating prior marijuana rescheduling petitions, "Congress established only one schedule, schedule I, for drugs of abuse with 'no currently accepted medical use in treatment in the United States' and 'lack of accepted safety for use . . . under medical supervision.' 21 U.S.C. 812(b)." 76 FR 40552 (2011); 66 FR 20038 (2001).

Basis for the Recommendation for Maintaining Marijuana in Schedule I of the Controlled Substances Act

On December 17, 2009, Mr. Bryan Krumm submitted a petition to the Drug Enforcement Administration (DEA) requesting that proceedings be initiated to repeal the rules and regulations that place marijuana[4] in Schedule I of the Controlled Substances Act (CSA). The petitioner contends that marijuana has an accepted medical use in the United States, has proven safety and efficacy, is safe for use under medical supervision, and does not have the abuse potential for placement in Schedule I. The petitioner requests that marijuana be rescheduled to any schedule other than Schedule I of the CSA. In May 2011, the DEA Administrator requested that the U.S. Department of Health and Human Services (HHS) provide a sdentific and medical evaluation of the available information and a scheduling recommendation for marijuana, in accordance with the provisions of 21 U.S.C. 811(b).

In accordance with 21 U.S.C. 811(b), the DEA has gathered information related to the control of marijuana *(Cannabis sativa)*[5] under the CSA. Pursuant to 21 U.S.C. 811(b), the Secretary of HHS is required to consider in a scientific and medical evaluation eight factors determinative of control under the CSA. Following consideration of the eight factors, if it is appropriate, the Secretary must make three findings to recommend scheduling a substance in the CSA or transferring a substance from one schedule to another. The findings relate to a substance's abuse potential, legitimate medical use, and safety or dependence liability. Administrative responsibilities for evaluating a substance for control under the CSA are performed by the Food and Drug Administration (FDA), with the concurrence of the National Institute on Drug Abuse (NIDA), as described in the Memorandum of Understanding (MOU) of March 8, 1985 (50 FR 9518–20).

In this document, FDA recommends continued control of marijuana in Schedule I of the CSA. Pursuant to 21 U.S.C. 811(c), the eight factors pertaining to the scheduling of marijuana are considered below.

1. Its Actual or Relative Potential for Abuse

Under the first factor the Secretary must consider marijuana's actual or relative potential for abuse. The CSA does not define the term "abuse." However, the CSA's legislative history suggests the following in determining whether a particular drug or substance has a potential for abuse:[6]

a. There is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community.

b. There is a significant diversion of the drug or drugs containing such a substance from legitimate drug channels.

c. Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice.

d. The drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

In the development of this scientific and medical evaluation for the purpose of scheduling, the Secretary analyzed considerable data related to the substance's abuse potential. The data include a discussion of the prevalence and frequency of use, the amount of the substance available for illicit use, the ease of obtaining or manufacturing the substance, the reputation or status of the substance "on the street," and evidence relevant to at-risk populations. Importantly, the petitioners define marijuana as including all *Cannabis* cultivated strains. Different marijuana samples derived from various cultivated strains may have very differernt chemical consituents, thus the analysis is based on what is known about the range of these constituents across all cultivated strains.

Determining the abuse potential of a substance is complex with many dimensions, and no single test or assessment provides a complete characterization. Thus, no single measure of abuse potential is ideal. Scientifically, a comprehensive evaluation of the relative abuse potential of a substance can include consideration of the following elements: Receptor binding affinity, preclinical pharmacology, reinforcing effects, discriminative stimulus effects, dependence producing potential, pharmacokinetics, route of administration, toxicity, data on actual abuse, clinical abuse potential studies, and public health risks. Importantly, abuse can exist independently from tolerance or physical dependence because individuals may abuse drugs in doses or patterns that don not induce these phenomena. Additionally evidence of clandestine population and illicit trafficking of a substance can shed light on both the demand for a substance as well as the ease of obtaining a substance. Animal and human laboratory data and epidemiological data are all used in determining a substance's abuse potential. Moreover, epidemiological data can indicate actual abuse.

The petitioner compares the effects of marijuana to currently controlled Schedule II substances and make repeated claims about their comparative effects. Comparisons between marijuana and the diverse array of Schedule II substances is difficult, because of the pharmacologically dissimilar actions of substances of Schedule II of the CSA. For example, Schedule II substances include stimulant-like drugs (*e.g.,* cocaine, methylphenidate, and amphetamine), opioids (*e.g.,* oxycodone, fentanyl), sedatives (*e.g.,* pentobarbital, amobarbital), dissociative anesthetics (*e.g.,* PCP), and naturally occurring plant components (*e.g.,* coca leaves and poppy straw). The mechanism(s) of action of the above Schedule II substances are wholly different from on another, and they are different from tetrahydrocannabinol (THC) and marijuana as well. For example, Schedule II stimulants typically function by increasing monoaminergic tone via an increase in dopamine and norepinephrine (Schmitt et al., 2013). In contrast, opioid analgesics function via mu-opioid receptor agonist effects.

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[4] Note that "marihuana" is the spelling originally used in the Controlled Substances Act (CSA). This document uses the spelling that is more common in current usage, "marijuana."

[5] The CSA defines marihuana (marijuana) as the following:

All parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination (21 U.S.C. 802(16)).

[6] Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91–1444, 91st Cong., Sess. 1 (1970) reprinted in U.S.C.C.A.N. 4566, 4603.

These differing mechanism(s) of action result in vastly different behavioral and adverse effect profiles, making comparisons across the range of pharmacologically diverse C–II substances inappropriate.

In addition, many substances scheduled under the CSA are reviewed and evaluated within the context of commercial drug development, using data submitted in the form of a new drug application (NDA). A new analgesic drug might be compared to a currently scheduled analgesic drug as part of the assessment of its relative abuse potential. However, because the petitioners have not identified a specific indication for the use of marijuana, identifying an appropriate comparator based on indication cannot be done.

a. There is evidence that individuals are taking the substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community.

Evidence shows that some individuals are taking marijuana in amounts sufficient to create a hazard to their health and to the safety of other individuals and the community. A large number of individuals use marijuana. HHS provides data on the extent of marijuana abuse through NIDA and the Substance Abuse and Mental Health Services Administration (SAMHSA). According to the most recent data from SAMHSA's 2012 National Survey on Drug Use and Health (NSDUH), which estimates the number of individuals who have use a substance within a month prior to the study (described as "current use"), marijuana is the most commonly used illicit drug among American aged 12 years and older, with an estimated 18.9 million Americans having used marijuana within the month prior to the 2012 NSDUH. Compared to 2004, when an estimated 14.6 million individuals reported using marijuana within the month prior to the study, the estimated rates in 2012 show an increase of approximately 4.3 million individuals. The 2013 Monitoring the Future (MTF) survey of 8th, 10th, and 12th grade students also indicates that marijuana is the most widely used illicit substance in this age group. Specifically, current month use was at 7.0 percent of 8th graders, 18.0 percent of 10th, graders and 22.7 percent of 12th graders. Additionally, the 2011 Treatment Episode Data Set (TEDS) reported that primary marijuana abuse accounted for 18.1 percent of non-private substance-abuse treatment facility admissions, with 24.3 percent of those admitted reporting daily use. However, of these admissions for primary marijuana abuse, the criminal justice system referred 51.6 percent to treatment. SAMHSA's Drug Abuse Warning Network (DAWN) was a national probability survey of U.S. hospitals with emergency departments (EDs) and was designed to obtain information on ED visits in which marijuana was mentioned, accounting for 36.4 percent of illicit drug related ED visits. There are some limitations related to DAWN data on ED visits, which are discussed in detail in Factor 4, "Its History and Current Pattern of Abuse;" Factor 5, "The Scope, Duration, and Significance of Abuse;" and Factor 6, "What, if an, Risk There is to the Public Health." These factors contain detailed discussions of these data.

A number of risks can occur with both acute and chronic use of marijuana. Detailed discussions of the risks are addressed in Factor 2, "Scientific Evidence of its Pharmacological Effect, if Known," and Factor 6, "What, if any, Risk There is to the Public Health."

b. There is significant diversion of the substance from legitimate drug channels.

There is a lack of evidence of significant diversion of marijuana from legitimate drug channels, but this is likely due to the fact that marijuana is more widely available from illicit sources rather than through legitimate channels. Marijuana is not an FDA-approved drug product, as an NDA or biologics license application (BLA) has not been approved for marketing in the United States. Numerous states and the District of Columbia have state-level medical marijuana laws that allow for marijuana use within that state. These state-level drug channels do not have sufficient collection of data related to medical treatment, including efficacy and safety.

Marijuana is used by researchers for nonclinical research as well as clinical research under investigational new drug (IND) applications; this represents the only legitimate drug channel in the United States. However, marijuana used for research reporesents a very small contribution of the total amount of marijuana available in the United States, and thus provides limited information about diversion. In addition, the lack of significant diversion of investigation supplies is likely because of the widespread availability of illicit marijuana of equal or greater amounts of delta^{9}-THC. The data originating from the DEA on seizure statistics demonstrate the magnitude of the availability for illicit marijuana. DEA's System to Retrieve Information from Drug Evidence (STRIDE) provides information on total domestic drug seizures, STRIDE reports a total domestic seizure of 573,195 kg of marijuana in 2011, the most recent year with complete data that is currently publically available (DEA Domestic Drug Seizures, n.d.).

c. Individuals are taking the substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such substances.

Because the FDA has not approved an NDA or BLA for a marijuana drug product for any therapeutic indication, the only way an individual can take marijuana on the basis of medical advice through legitimate channels at the federal level is by participating in research under an IND application. That said, numerous states and the District of Columbia have passed state-level medical marijuana laws allowing for individuals to use marijuana under certain cicrumstances. However, data are not yet available to determine the number of individuals using marijuana under these state-level medical marijuana laws. Regardless, according to the 2012 NSDUH data, 18.9 million American adults currently use marijuana (SAMHSA, 2013). Based on the large number of individuals reporting current use of marijuana and the lack of an FDA-approved drug product in the United States, one can assume that it is likely that the majority of individuals using marijuana do so on their own initiative rather than on the basis of medical advice from a licensed practitioner.

d. The substance is so related in its action to a substance already listed as having a potential for abuse to make it likely that it will have the same potential for abuse as such substance, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

FDA has approved two drug products containing cannabinoid compounds that are structurally related to the active components in marijuana. These two marketed products are controlled under the CSA. Once a specific drug product containing cannabinoids becomes approved, that specific drug product may be moved from Schedule I to a different Schedule (II–V) under the CSA. Firstly, Marinol—generically known as dronabinol—is a Schedule III drug product containing synthetic delta^{9}-THC. Marinol, which is formulated in sesame oil in soft gelatin capsules, was first placed in Schedule II under the CSA following its approval by the FDA. Marinol was later rescheduled to Schedule III under the CSA because of low numbers of reports of abuse relative to marijuana. Dronabinol is listed in Schedule I under the CSA. FDA approved Marinol in 1985 for the treatment of nausea and vomiting associated with cancer chemotherapy in patients who failed to respond adequately to conventional anti-emetic treatments. In 1992, FDA approved Marional for anorexia associated with weight loss in patients with acquired immunodeficiency syndrome (AIDS). Secondly, in 1985, FDA approved Cesamet, a drug product containing the Schedule II substance nabilone, for the treatment of nausea and vomiting associated with cancer chemotherapy. Besides the two cannabinoid-containing drug products FDA approved for marketing, other naturally occurring cannabinoids and their derivatives (from *Cannabis*) and their synthetic equivalents with similar chemical structure and pharmacological activity are included in the CSA as Schedule I substances.

2. Scientific Evidence of Its Pharmacological Effects, if Known

Under the second factor, the Secretary must consider the scientific evidence of marijuana's pharmacological effects. Abundant scientific data are available on the neurochemistry, toxicology, and pharmacology of marijuana. This section includes a scientific evaluation of marijuana's neurochemistry; pharmacology; and human and animal behavioral, central nervous system, cognitive, cardiovascular, autonomic, endocrinological, and immunological system effects. The overview presented below relies upon the most current research literature on cannabinoids.

Neurochemistry and Pharmacology of Marijuana

Marijuana is a plant that contains numerous natural constituents, such as cannabinoids, that have a variety of pharmacological actions. The petition defines marijuana as including all Cannabis cultivated strains. Different marijuana samples derived from various cultivated strains may have very different chemical constituents including delta^9-THC and other cannabinoids (Appendino et al., 2011). As a consequence, marijuana products from different strains will have different biological and pharmacological profiles.

According to ElSohly and Slade (2005) and Appendino et al. (2011), marijuana contains approximately 525 identified natural constituents, including approximately 100 compounds classified as cannabinoids. Cannabinoids primarily exist in Cannabis, and published data suggests that most major cannabinoid compounds occurring naturally have been identified chemically. New and minor cannabinoids and other new compounds are continuously being characterized (Pollastro et al., 2011). So far, only two cannabinoids (cannabigerol and its corresponding acid) have been obtained from a non-Cannabis source. A South African *Helichrysum* (*H. umbraculigerum*) accumulates these compounds (Appendino et al., 2011). The chemistry of marijuana is described in more detail in Factor 3, "The State of Current Scientific Knowledge Regarding the Drug or Other Substance."

The site of cannabinoid action is at the cannabinoid receptors. Cloning of cannabinoid receptors, first from rat brain tissue (Matsuda et al., 1990) and then from human brain tissue (Gerard et al., 1991), has verified the site of action. Two cannabinoid receptors, CB$_1$ and CB$_2$, were characterized (Battista et al., 2012; Piomelli, 2005). Evidence of a third cannabinoid receptor exists, but it has not been identified (Battista et al., 2012).

The cannabinoid receptors, CB$_1$ and CB$_2$, belong to the family of G-protein-coupled receptors, and present a typical seven transmembrane-spanning domain structure. Cannabinoid receptors link to an inhibitory G-protein (G$_i$), such that adenylate cyclase activity is inhibited when a ligand binds to the receptor. This, in tum, prevents the conversion of ATP to the second messenger, cyclic AMP (cAMP). Examples of inhibitory coupled receptors include opioid, muscarinic cholinergic, alpha$_2$-adrenoreceptors, dopamine (D$_2$), and serotonin (5-HT$_1$).

Cannabinoid receptor activation inhibits N- and P/Q-type calcium channels and activates inwardly rectifying potassium channels (Mackie et al., 1995; Twitchell et al., 1997). N-type calcium channel inhibition decreases neurotransmitter release from several tissues. Thus, calcium channel inhibition may be the mechanism by which cannabinoids inhibit acetylcholine, norepinephrine, and glutamate release from specific areas of the brain. These effects may represent a potential cellular mechanism underlying cannabinoids' antinociceptive and psychoactive effects (Ameri, 1999).

CB$_1$ receptors are found primarily in the central nervous system, but are also present in peripheral tissues. CB$_1$ receptors are located mainly in the basal ganglia, hippocarnpus, and cerebellum of the brain (Howlett et al., 2004). The localization of these receptors may explain cannabinoid interference with movement coordination and effects on memory and cognition. Additionally, CB$_1$ receptors are found in the immune system and numerous other peripheral tissues (Petrocellis and Di Marzo, 2009). However, the concentration of CB$_1$ receptors is considerably lower in peripheral tissues than in the central nervous system (Herkenharn et al., 1990 and 1992).

CB$_2$ receptors are found primarily in the immune system, but are also present in the central nervous system and other peripheral tissues. In the immune system, CB$_2$ receptors are found predominantly in B lymphocytes and natural killer cells (Bouaboula et al., 1993). CB$_2$ receptors may mediate cannabinoids' immunological effects (Galiegue et al., 1995). Additionally, CB$_2$ receptors have been localized in the brain, primarily in the cerebellum and hippocampus (Gong et al., 2006). The distribution of CB$_2$ receptors throughout the body is less extensive than the distribution of CB$_1$ receptors (Petrocellis and Di Marzo, 2009). However, both CB$_1$ and CB$_2$ receptors are present in numerous tissues of the body.

Cannabinoid receptors have endogenous ligands. In 1992 and 1995, two endogenous cannabinoid receptor agonists, anandamide and arachidonyl glycerol (2-AG), respectively, were identified (Di Marzo, 2006). Anandamide is a low efficacy agonist (Breivogel and Childers, 2000) and 2-AG is a high efficacy agonist (Gonsiorek et al., 2000). Cannabinoid endogenous ligands are present in central as well as peripheral tissues. A combination of uptake and hydrolysis terminate the action of the endogenous ligands. The endogenous cannabinoid system is a locally active signaling system that, to help restore homeostasis, is activated "on demand" in response to changes to the local homeostasis (Petrocellis and Di Marzo, 2009). The endogenous cannabinoid system, including the endogenous cannabinoids and the cannabinoid receptors, demonstrate substantial plasticity in response to several physiological and pathological stimuli (Petrocellis and Di Marzo, 2009). This plasticity is particularly evident in the central nervous system.

Delta^9-THC and cannabidiol (CBD) are two abundant cannabinoids present in marijuana. Marijuana's major psychoactive cannabinoid is delta^9-THC (Wachtel et al., 2002). In 1964, Gaoni and Mechoularn first described delta^9-THC's structure and function. In 1963, Mechoularn and Shvo first described CBD's structure. The pharmacological actions of CBD have not been fully studied in humans.

Delta^9-THC and CBD have varying affinity and effects at the cannabinoid receptors. Delta^9-THC displays similar affinity for CB_1 and CB_2 receptors, but behaves as a weak agonist for CB_2 receptors. The identification of synthetic cannabinoid ligands that selectively bind to CB_2 receptors but do not have the typical delta^9-THC-like psychoactive properties suggests that the activation of CB_1-receptors mediates cannabinoids' psychotropic effects (Hanus et al., 1999). CBD has low affinity for both CB_1 and CB_2 receptors (Mechoulam et al., 2007). According to Mechoulam et al. (2007), CBD has antagonistic effects at CB_1 receptors and some inverse agonistic properties at CB_2 receptors. When cannabinoids are given subacutely to rats, CB_1 receptors down-regulate and the binding of the second messenger system coupled to CB_1 receptors, GTPgarnmaS, decreases (Breivogel et al., 2001).

Animal Behavioral Effects

Self-Administration

Self-administration is a method that assesses the ability of a drug to produce rewarding effects. The presence of rewarding effects increases the likelihood of behavioral responses to obtain additional drug. Animal self-administration of a drug is often useful in predicting rewarding effects in humans, and is indicative of abuse liability. A good correlation is often observed between those drugs that rhesus monkeys self-administer and those drugs that humans abuse (Balster and Bigelow, 2003). Initially, researchers could not establish self-administration of cannabinoids, including delta^9-THC, in animal models. However, self-administration of delta^9-THC can now be established in a variety of animal models under specific training paradigms (Justinova et al., 2003, 2004, 2005).

Squirrel monkeys, with and without prior exposure to other drugs of abuse, self-administer delta^9-THC under specific conditions. For instance, Tanda et al. (2000) observed that when squirrel monkeys are initially trained to self-administer intravenous cocaine, they will continue to bar-press delta^9-THC at the same rate as they would with cocaine. The doses were notably comparable to those doses used by humans who smoke marijuana. SR141716, a CB_1 cannabinoid receptor agonist-antagonist, can block this rewarding effect. Other studies show that naïve squirrel monkeys can be successfully trained to self-administer delta^9-THC intravenously (Justinova et al., 2003). The maximal responding rate is 4 μg/kg per injection, which is 2–3 times greater than observed in previous studies using cocaine-experienced monkeys. Naltrexone, a mu-opioid antagonist, partially antagonizes these rewarding effects of delta^9-THC (Justinova et al., 2004).

Additionally, data demonstrate that under specific conditions, rodents self-administer cannabinoids. Rats will self-administer delta^9-THC when applied intracerebroventricularly (i.c.v.), but only at the lowest doses tested (0.01–0.02 μg/infusion) (Braida et al., 2004). SR141716 and the opioid antagonist naloxone can antagonize this effect. However, most studies involve rodents self-administrating the synthetic cannabinoid WIN 55212, a CB_1 receptor agonist with a non-cannabinoid structure (Deiana et al., 2007; Fattore et al., 2007; Martellotta et al., 1998; Mendizabal et al., 2006).

Aversive effects, rather than reinforcing effects, occur in rats that received high doses of WIN 55212 (Chaperon et al., 1998) or delta^9-THC (Sanudo-Pena et al., 1997), indicating a possible critical dose-dependent effect. In both studies, SR141716 reversed these aversive effects.

Conditioned Place Preference

Conditioned place preference (CPP) is a less rigorous method than self-administration for determining whether or not a drug has rewarding properties. In this behavioral test, animals spend time in two distinct environments: One where they previously received a drug and one where they received a placebo. If the drug is reinforcing, animals will choose to spend more time in the environment paired with the drug, rather than with the placebo, when presented with both options simultaneously.

Animals show CPP to delta^9-THC, but only at the lowest doses tested (0.075–1.0 mg/kg, intraperitoneal (i.p.)) (Braida et al., 2004). SR141716 and naloxone antagonize this effect (Braida et al., 2004). As a partial agonist, SR141716 can induce CPP at doses of 0.25, 0.5, 2 and 3 mg/kg (Cheer et al., 2000). In knockout mice, those without μ-opioid receptors do not develop CPP to delta^9-THC (Ghozland et al., 2002).

Drug Discrimination Studies

Drug discrimination is a method where animals indicate whether a test drug produces physical or psychic perceptions similar to those produced by a known drug of abuse. In this test, an animal learns to press one bar when it receives the known drug of abuse and another bar when it receives placebo. To determine whether the test drug is like the known drug of abuse, a challenge session with the test drug demonstrates which of the two bars the animal presses more often.

In addition to humans (Lile et al., 2009; Lile et al., 2011), it has been noted that animals, including monkeys (McMahon, 2009), mice (McMahon et al., 2008), and rats (Gold et al., 1992), are able to discriminate cannabinoids from other drugs or placebo. Moreover, the major active metabolite of delta^9-THC, 11-hydroxy-delta^9-THC, also generalizes (following oral administration) to the stimulus cues elicited by delta^9-THC (Browne and Weissman, 1981). Twenty-two other cannabinoids found in marijuana also fully substitute for delta^9-THC. However, CBD does not substitute for delta^9-THC in rats (Vann et al., 2008).

Discriminative stimulus effects of delta^9-THC are pharmacologically specific for marijuana containing cannabinoids (Balster and Prescott, 1992; Browne and Weissman, 1981; Wiley et al., 1993, 1995). The discriminative stimulus effects of the cannabinoid group appear to provide unique effects because stimulants, hallucinogens, opioids, benzodiazepines, barbiturates, NMDA antagonists, and antipsychotics do not fully substitute for delta^9-THC.

Central Nervous System Effects

Human Physiological and Psychological Effects

Psychoactive Effects

Below is a list of the common subjective responses to cannabinoids (Adams and Martin, 1996; Gonzalez, 2007; Hollister 1986, 1988; Institute of Medicine, 1982). According to Maldonado (2002), these responses to marijuana are pleasurable to many humans and are often associated with drug-seeking and drug-taking. High levels of positive psychoactive effects are associated with increased marijuana use, abuse, and dependence (Scherrer et al., 2009; Zeiger et al., 2010).

(1) Disinhibition, relaxation, increased sociability, and talkativeness.

(2) Increased merriment and appetite, and even exhilaration at high doses.

(3) Enhanced sensory perception, which can generate an increased appreciation of music, art, and touch.

(4) Heightened imagination, which can lead to a subjective sense of increased creativity.

(5) Initial dizziness, nausea, tachycardia, facial flushing, dry mouth, and tremor.

(6) Disorganized thinking, inability to converse logically, time distortions, and short-term memory impairment.

(7) Ataxia and impaired judgment, which can impede driving ability or lead to an increase in risk-tasking behavior.

(8) Illusions, delusions, and hallucinations that intensify with higher doses.

(9) Emotional lability, incongruity of affect, dysphoria, agitation, paranoia, confusion, drowsiness, and panic attacks, which are more common in inexperienced or high-dosed users.

As with many psychoactive drugs, a person's medical, psychiatric, and drug-taking history can influence the individual's response to marijuana. Dose preferences to marijuana occur in that marijuana users prefer higher concentrations of the principal psychoactive substance (1.95 percent delta^{9}-THC) over lower concentrations (0.63 percent delta^{9}-THC) (Chait and Burke, 1994). Nonetheless, frequent marijuana users (≤100 times of use) were able to identify a drug effect from low-dose delta^{9}-THC better than occasional users (<10 times of use) while also experiencing fewer sedative effects from marijuana (Kirk and de Wit, 1999).

The petitioners contend that many of marijuana's naturally occurring cannabinoids mitigate the psychoactive effects of delta^{9}-THC, and therefore that marijuana lacks sufficient abuse potential to warrant Schedule I placement, because Marinol, which is in Schedule III, contains only delta^{9}-THC. This theory has not been demonstrated in controlled studies. Moreover, the concept of abuse potential encompasses all properties of a substance, including its chemistry, pharmacology, and pharmacokinetics, as well as usage patterns and diversion history. The abuse potential of a substance is associated with the repeated or sporadic use of a substance in nonmedical situations for the psychoactive effects the substance produces. These psychoactive effects include euphoria, perceptual and other cognitive distortions, hallucinations, and mood changes. However, as stated above, the abuse potential not only includes the psychoactive effects, but also includes other aspects related to a substance.

DEA's final published rule entitled "Rescheduling of the Food and Drug Administration Approved Product Containing Synthetic Dronabinol [(−)-delta^{9}-(trans)-Tetrahydrocannabinol] in Sesame Oil and Encapsulated in Soft Gelatin Capsules From Schedule II to Schedule III" (64 FR 35928, July 2, 1999) rescheduled Marinol from Schedule II to Schedule III. The HHS assessment of the abuse potential and subsequent scheduling recommendation compared Marinol to marijuana on different aspects related to abuse potential. Major differences in formulation, availability, and usage between marijuana and the drug product, Marinol, contribute to their differing abuse potentials.

Hollister and Gillespie (1973) estimated that delta^{9}-THC by smoking is 2.6 to 3 times more potent than delta^{9}-THC ingested orally. The intense psychoactive drug effect achieved, rapidly by smoking is generally considered to produce the effect desired by the abuser. This effect explains why abusers often prefer to administer certain drugs by inhalation, intravenously, or intranasally rather than orally. Such is the case with cocaine, opium, heroin, phencyclidine, methamphetamine, and delta^{9}-THC from marijuana (0.1–9.5 percent delta^{9}-THC range) or hashish (10–30 percent delta^{9}-THC range) (Wesson and Washburn, 1990). Thus, the delayed onset and longer duration of action for Marinol may be contributing factors limiting the abuse or appeal of Marinol as a drug of abuse relative to marijuana.

The formulation of Marinol is a factor that contributes to differential scheduling of Marinol and marijuana. For example, extraction and purification of dronabinol from the encapsulated sesame oil mixture of Marinol is highly complex and difficult. Additionally, the presence of sesame oil mixture in the formulation may preclude the smoking of Marinol-laced cigarettes.

Additionally, there is a dramatic difference between actual abuse and illicit trafficking of Marinol and marijuana. Despite Marinol's availability in the United States, there have been no significant reports of abuse, diversion, or public health problems due to Marinol. By comparison, 18.9 million American adults report currently using marijuana (SAMHSA, 2013).

In addition, FDA's approval of an NDA for Marinol allowed for Marinol to be rescheduled to Schedule II, and subsequently to Schedule III of the CSA. In conclusion, marijuana and Marinol differ on a wide variety of factors that contribute to each substance's abuse potential. These differences are major reasons distinguishing the higher abuse potential for marijuana and the different scheduling determinations of marijuana and Marinol.

In terms of the petitioners' claim that different cannabinoids present in marijuana mitigate the psychoactive effects of delta^{9}-THC, only three of the cannabinoids present in marijuana were simultaneously administered with delta^{9}-THC to examine how the combinations of these cannabinoids such as CBD, cannabichromene (CBC) and cannabinol (CBN) influence delta^{9}-THC's psychoactive effects. Dalton et al. (1976) observed that smoked administration of placebo marijuana cigarettes containing injections of 0.15 mg/kg CBD combined with 0.025mg/kg of delta^{9}-THC, in a 7:1 ratio of CBD to delta^{9}-THC, significantly decreased ratings of acute subjective effects and "high" when compared to smoking delta^{9}-THC alone. In contrast, Ilan et al. (2005) calculated the naturally occurring concentrations of CBC and CBD in a batch of marijuana cigarettes with either 1.8 percent or 3.6 percent delta^{9}-THC concentration by weight. For each strength of delta^{9}-THC in marijuana cigarettes, the concentrations of CBC and CBD were classified in groups of either low or high. The study varied the amount of CBC and CBD within each strength of delta^{9}-THC marijuana cigarettes, with administrations consisting of either low CBC (between 0.1–0.2 percent CBC concentration by weight) and low CBD (between 0.1–0.4 percent CBD concentration by weight), high CBC (≤ 0.5 percent CBC concentration by weight) and low CBD, or low CBC and high CBD (≤1.0 percent CBD concentration by weight). Overall, all combinations scored significantly greater than placebo on ratings of subjective effects, and there was no significant difference between any combinations.

The oral administration of a combination of either 15, 30, or 60 mg CBD with 30 mg delta^{9}-THC dissolved in liquid (in a ratio of at least 1:2 CBD to delta^{9}-THC) reduced the subjective effects produced by delta^{9}-THC alone (Karniol et al., 1974). Additionally, orally administering a liquid mixture combining 1 mg/kg CBD with 0.5 mg/kg of delta^{9}-THC (ratio of 2:1 CBD to delta^{9}-THC) decreased scores of anxiety and marijuana drug effect on the Addiction Research Center Inventory (ARCI) compared to delta^{9}-THC alone (Zuardi et al., 1982). Lastly, oral administration of either 12.5, 25, or 50 mg CBN combined with 25 mg delta^{9}-THC dissolved in liquid (ratio of at least 1:2 CBN to delta^{9}-THC) significantly increased subjective ratings of "drugged," "drowsy," "dizzy," and "drunk," compared to delta^{9}-THC alone (Karniol et al., 1975).

Even though some studies suggest that CBD may decrease some of delta^{9}-THC's psychoactive effects, the ratios of CBD to delta^{9}-THC administered in these studies are not present in marijuana used by most people. For example, in one study, researchers used smoked marijuana with ratios of CBD to delta^9-THC naturally present in marijuana plant material and they found out that varying the amount of CBD actually had no effect on delta^9-THC's psychoactive effects (Ilan et al., 2005). Because most marijuana currently available on the street has high amounts of delta^9-THC with low amounts of CBD and other cannabinoids, most individuals use marijuana with low levels of CBD present (Mehmedic et al., 2010). Thus, any possible mitigation of delta^9-THC's psychoactive effects by CBD will not occur for most marijuana users. In contrast, one study indicated that another cannabinoid present in marijuana, CBN, may enhance delta^9-THC's psychoactive effects (Karniol et al., 1975).

Behavioral Impairment

Marijuana induces various psychoactive effects that can lead to behavioral impairment. Marijuana's acute effects can significantly interfere with a person's ability to learn in the classroom or to operate motor vehicles. Acute administration of smoked marijuana impairs performance on learning, associative processes, and psychomotor behavioral tests (Block et al., 1992). Ramaekers et al. (2006a) showed that acute administration of 250 μg/kg and 500 μg/kg of delta^9-THC in smoked marijuana dose-dependently impairs cognition and motor control, including motor impulsivity and tracking impairments (Ramaekers et al., 2006b). Similarly, administration of 290 μg/kg delta^9-THC in a smoked marijuana cigarette resulted in impaired perceptual motor speed and accuracy: Two skills which are critical to driving ability (Kurzthaler et al., 1999). Lastly, administration of 3.95 percent delta^9-THC in a smoked marijuana cigarette not only increased disequilibrium measures, but also increased the latency in a task of simulated vehicle braking at a rate comparable to an increase in stopping distance of five feet at 60 mph (Liguori et al., 1998). However, acute administration of marijuana containing 2.1 percent delta^9-THC does not produce "hangover effects" (Chait, 1990).

In addition to measuring the acute effects immediately following marijuana administration, researchers have conducted studies to determine how long behavioral impairments last after abstinence. Some of marijuana's acute effects may not fully resolve until at least one day after the acute psychoactive effects have subsided. Heishman et al. (1990) showed that impairment on memory tasks persists for 24 hours after smoking marijuana cigarettes containing 2.57 percent delta^9-THC. However, Fant et al. (1998) showed that the morning after exposure to 1.8 percent or 3.6 percent smoked delta^9-THC, subjects had minimal residual alterations in subjective or performance measures.

A number of factors may influence marijuana's behavioral effects including the duration of use (chronic or short term), frequency of use (daily, weekly, or occasionally), and amount of use (heavy or moderate). Researchers also have examined how long behavioral impairments last following chronic marijuana use. These studies used self-reported histories of past duration, frequency, and amount of past marijuana use, and administered a variety of performance and cognitive measures at different time points following marijuana abstinence. In chronic marijuana users, behavioral impairments may persist for up to 28 days of abstinence. Solowij et al. (2002) demonstrated that after 17 hours of abstinence, 51 adult heavy chronic marijuana users performed worse on memory and attention tasks than 33 non-using controls or 51 heavy, short-term users. Another study noted that heavy, frequent marijuana users, abstinent for at least 24 hours, performed significantly worse than the controls on verbal memory and psychomotor speed tests (Messinis et al., 2006). Additionally, after at least 1 week of abstinence, young adult frequent marijuana users, aged 18–28, showed deficits in psychomotor speed, sustained attention, and cognitive inhibition (Lisdahl and Price, 2012). Adult heavy, chronic marijuana users showed deficits on memory tests after 7 days of supervised abstinence (Pope et al., 2002). However, when these same individuals were again tested after 28 days of abstinence, they did not show significant memory deficits. The authors concluded, "cannabis-associated cognitive deficits are reversible and related to recent cannabis exposure, rather than irreversible and related to cumulative lifetime use." [7] However, other researchers reported neuropsychological deficits in memory, executive functioning, psychomotor speed and manual dexterity in heavy marijuana users abstinent for 28 days (Bolla et al., 2002). Furthermore, a follow-up study of heavy marijuana users noted decision-making deficits after 25 days of supervised abstinence. (Bolla et al., 2005). However, moderate marijuana users did not show decision-making deficits after 25 days of abstinence, suggesting the amount of marijuana use may impact the duration of residual impairment.

The effects of chronic marijuana use do not seem to persist after more than 1 to 3 months of abstinence. After 3 months of abstinence, any deficits observed in IQ, immediate memory, delayed memory, and information-processing speeds following heavy marijuana use compared to pre-drug use scores were no longer apparent (Fried et al., 2005). Marijuana did not appear to have lasting effects on performance of a comprehensive neuropsychological battery when 54 monozygotic male twins (one of whom used marijuana, one of whom did not) were compared 1–20 years after cessation of marijuana use (Lyons et al., 2004). Similarly, following abstinence for a year or more, both light and heavy adult marijuana users did not show deficits on scores of verbal memory compared to non-using controls (Tait et al., 2011). According to a recent meta-analysis looking at non-acute and long-lasting effects of marijuana use on neurocognitive performance, any deficits seen within the first month following abstinence are generally not present after about 1 month of abstinence (Schreiner and Dunn, 2012).

Another aspect that may be a critical factor in the intensity and persistence of impairment resulting from chronic marijuana use is the age of first use. Individuals with a diagnosis of marijuana misuse or dependence who were seeking treatment for substance use, who initiated marijuana use before the age of 15 years, showed deficits in performance on tasks assessing sustained attention, impulse control, and general executive functioning compared to non-using controls. These deficits were not seen in individuals who initiated marijuana use after the age of 15 years (Fontes et al., 2011). Similarly, heavy, chronic marijuana users who began using marijuana before the age of 16 years had greater decrements in executive functioning tasks than heavy, chronic marijuana users who started using after the age of 16 years and non-using controls (Gruber et al., 2012). Additionally, in a prospective longitudinal birth cohort study of 1,037 individuals, marijuana dependence or chronic marijuana use was associated with a decrease in IQ and general neuropsychological performance compared to pre-marijuana exposure levels in adolescent onset users (Meier et al., 2012). The decline in adolescent-onset user's IQ persisted even after reduction or abstinence of marijuana use for at least 1 year. In contrast, the adult-onset chronic marijuana users showed no significant changes in IQ compared to pre-exposure levels whether they were current users or abstinent for at least 1 year (Meier et al., 2012).

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[7] In this quotation the term *Cannabis* is used interchangeably for *marijuana.*

In addition to the age of onset of use, some evidence suggests that the amount of marijuana used may relate to the intensity of impairments. In the above study by Gruber et al. (2012), where early-onset users had greater deficits than late-onset users, the early-onset users reported using marijuana twice as often and using three times as much marijuana per week than the late-onset users. Meier et al. (2012) showed that the deficits in IQ seen in adolescent-onset users increased with the amount of marijuana used. Moreover, when comparing scores for measures of IQ, immediate memory, delayed memory, and information-processing speeds to pre-drug-use levels, the current, heavy, chronic marijuana users showed deficits in all three measures while current, occasional marijuana users did not (Fried et al., 2005).

Behavioral Effects of Prenatal Exposure

Studies with children at different stages of development are used to examine the impact of prenatal marijuana exposure on performance in a series of cognitive tasks. However, many pregnant women who reported marijuana use were more likely to also report use of alcohol, tobacco, and cocaine (Goldschmidt et al., 2008). Thus, with potential exposure to multiple drugs, it is difficult to determine the specific impact of prenatal marijuana exposure.

Most studies assessing the behavioral effects of prenatal marijuana exposure included women who, in addition to using marijuana, also reported using alcohol and tobacco. However, some evidence suggests an association between heavy prenatal marijuana exposure and deficits in some cognitive domains. In both 4-year-old and 6-year-old children, heavy prenatal marijuana use is negatively associated with performance on tasks assessing memory, verbal reasoning, and quantitative reasoning (Fried and Watkinson, 1987; Goldschmidt et al., 2008). Additionally, heavy prenatal marijuana use is associated with deficits in measures of sustained attention in children at the ages of 6 years and 13–16 years (Fried et al., 1992; Fried, 2002). In 9- to 12-year-old children, prenatal marijuana exposure is negatively associated with executive functioning tasks that require impulse control, visual analysis, and hypothesis (Fried et al., 1998).

Association of Marijuana Use With Psychosis

This analysis evaluates only the evidence for a direct link between prior marijuana use and the subsequent development of psychosis. Thus, this discussion does not consider issues such as whether marijuana's transient effects are similar to psychotic symptoms in healthy individuals or exacerbate psychotic symptoms in individuals already diagnosed with schizophrenia.

Extensive research has been conducted to investigate whether exposure to marijuana is associated with the development of schizophrenia or other psychoses. Although many studies are small and inferential, other studies in the literature use hundreds to thousands of subjects. At present, the available data do not suggest a causative link between marijuana use and the development of psychosis (Minozzi et al., 2010). Numerous large, longitudinal studies show that subjects who used marijuana do not have a greater incidence of psychotic diagnoses compared to those who do not use marijuana (Fergusson et al., 2005; Kuepper et al., 2011; Van Os et al., 2002).

When analyzing the available evidence of the connection between psychosis and marijuana, it is critical to determine whether the subjects in the studies are patients who are already diagnosed with psychosis or individuals who demonstrate a limited number of symptoms associated with psychosis without qualifying for a diagnosis of the disorder. For example, instead of using a diagnosis of psychosis, some researchers relied on non-standard methods of representing symptoms of psychosis including ''schizophrenic cluster'' (Maremmani et al., 2004), ''subclinical psychotic symptoms'' (Van Gastel et al., 2012), ''pre-psychotic clinical high risk'' (Van der Meer et al., 2012), and symptoms related to ''psychosis vulnerability'' (Griffith-Lendering et al., 2012). These groupings do not conform to the criteria in the Diagnostic and Statistical Manual (DSM–5) or the International Classification of Diseases (ICD–10) for a diagnosis of psychosis. Thus, these groupings are not appropriate for use in evaluating marijuana's impact on the development of actual psychosis. Accordingly, this analysis includes only those studies that use subjects diagnosed with a psychotic disorder.

In the largest study evaluating the link between psychosis and drug use, 274 of the approximately 45,500 Swedish conscripts in the study population (<0.01 percent) received a diagnosis of schizophrenia within the 14-year period following military induction from 1969 to 1983 (Andreasson et al., 1987). Of the conscripts diagnosed with psychosis, 7.7 percent (21 of the 274 conscripts with psychosis) had used marijuana more than 50 times at induction, while 72 percent (197 of the 274 conscripts with psychosis) had never used marijuana. Although high marijuana use increased the relative risk for schizophrenia to 6.0, the authors note that substantial marijuana use history ''accounts for only a minority of all cases'' of psychosis (Andreasson et al., 1987). Instead, the best predictor for whether a conscript would develop psychosis was a non-psychotic psychiatric diagnosis upon induction. The authors concluded that marijuana use increased the risk for psychosis only among individuals predisposed to develop the disorder. In addition, a 35-year follow up to this study reported very similar results (Manrique-Garcia et al., 2012). In this follow up study, 354 conscripts developed schizophrenia; of these 354 conscripts, 32 used marijuana more than 50 times at induction (9 percent, an odds ratio of 6.3), while 255 had never used marijuana (72 percent).

Additionally, the conclusion that the impact of marijuana may manifest only in individuals likely to develop psychotic disorders has been shown in many other types of studies. For example, although evidence shows that marijuana use may precede the presentation of symptoms in individuals later diagnosed with psychosis (Schimmelmann et al., 2011), most reports conclude that prodromal symptoms of schizophrenia appear prior to marijuana use (Schiffman et al., 2005). Similarly, a review of the gene-environment interaction model for marijuana and psychosis concluded that some evidence supports marijuana use as a factor that may influence the development of psychosis, but only in those individuals with psychotic liability (Pelayo-Teran et al., 2012).

A similar conclusion was drawn when the prevalence of schizophrenia was modeled against marijuana use across eight birth cohorts in Australia in individuals born between the years 1940 to 1979 (Degenhardt et al., 2003). Although marijuana use increased over time in adults born during the four-decade period, there was not a corresponding increase in diagnoses for psychosis in these individuals. The authors conclude that marijuana may precipitate schizophrenic disorders only in those individuals who are vulnerable to developing psychosis. Thus, marijuana *per se* does not appear to induce schizophrenia in the majority of individuals who have tried or continue to use marijuana. However, in individuals with a genetic vulnerability for psychosis, marijuana use may influence the development of psychosis.

Cardiovascular and Autonomic Effects

Single smoked or oral doses of delta^9-THC produce tachycardia and may increase blood pressure (Capriotti et al., 1988; Benowitz and Jones, 1975). Some evidence associates the tachycardia produced by delta^9-THC with excitation of the sympathetic and depression of the parasympathetic nervous systems (Malinowska et al., 2012). During chronic marijuana ingestion, a tolerance to tachycardia develops (Malinowska et al., 2012).

However, prolonged delta^9-THC ingestion produces bradycardia and hypotension (Benowitz and Jones, 1975). Plant-derived cannabinoids and endocannabinoids elicit hypotension and bradycardia via activation of peripherally-located CB_1 receptors (Wagner et al., 1998). Specifically, the mechanism of this effect is through presynaptic CB1 receptor-mediated inhibition of norepinephrine release from peripheral sympathetic nerve terminals, with possible additional direct vasodilation via activation of vascular cannabinoid receptors (Pacher et al., 2006). In humans, tolerance can develop to orthostatic hypotension (Jones, 2002; Sidney, 2002) possibly related to plasma volume expansion, but tolerance does not develop to the supine hypotensive effects (Benowitz and Jones, 1975). Additionally, electrocardiographic changes are minimal, even after large cumulative doses of delta^9-THC are administered. (Benowitz and Jones, 1975).

Marijuana smoking by individuals, particularly those with some degree of coronary artery or cerebrovascular disease, poses risks such as increased cardiac work, catecholamines and carboxyhemoglobin, myocardial infarction, and postural hypotension (Benowitz and Jones, 1981; Hollister, 1988; Mittleman et al., 2001; Malinowska et al., 2012).

Respiratory Effects

After acute exposure to marijuana, transient bronchodilation is the most typical respiratory effect (Gong et al., 1984). A recent 20-year longitudinal study with over 5,000 individuals collected information on the amount of marijuana use and pulmonary function data at years 0, 2, 5, 10, and 20 (Pletcher et al., 2012). Among the more than 5,000 individuals who participated in the study, almost 800 of them reported current marijuana use but not tobacco use at the time of assessment. Pletcher et al. (2012) found that the occasional use of marijuana is not associated with decreased pulmonary function. However, some preliminary evidence suggests that heavy marijuana use may be associated with negative pulmonary effects (Pletcher et al., 2012). Long-term use of marijuana can lead to chronic cough and increased sputum, as well as an increased frequency of chronic bronchitis and pharyngitis. In addition, pulmonary function tests reveal that large-airway obstruction can occur with chronic marijuana smoking, as can cellular inflammatory histopathological abnormalities in bronchial epithelium (Adams and Martin 1996; Hollister 1986).

Evidence regarding marijuana smoking leading to cancer is inconsistent, as some studies suggest a positive correlation while others do not (Lee and Hancox, 2011; Tashkin, 2005). Several lung cancer cases have been reported in young marijuana users with no tobacco smoking history or other significant risk factors (Fung et al., 1999). Marijuana use may dose-dependently interact with mutagenic sensitivity, cigarette smoking, and alcohol use to increase the risk of head and neck cancer (Zhang et al., 1999). However, in a large study with 1,650 subjects, a positive association was not found between marijuana and lung cancer (Tashkin et al., 2006). This finding remained true, regardless of the extent of marijuana use, when controlling for tobacco use and other potential confounding variables. Overall, new evidence suggests that the effects of marijuana smoking on respiratory function and carcinogenicity differ from those of tobacco smoking (Lee and Hancox, 2011).

Endocrine System

Experimental marijuana administration to humans does not consistently alter many endocrine parameters. In an early study, male subjects who experimentally received smoked marijuana showed a significant depression in luteinizing hormone and a significant increase in cortisol (Cone et al., 1986). However, two later studies showed no changes in hormones. Male subjects experimentally exposed to smoked delta^9-THC (18 mg/marijuana cigarette) or oral delta^9-THC (10 mg three times per day for 3 days and on the morning of the fourth day) showed no changes in plasma adrenocorticotropic hormone (ACTH), cortisol, prolactin, luteinizing hormone, or testosterone levels (Dax et al., 1989). Similarly, a study with 93 men and 56 women showed that chronic marijuana use did not significantly alter concentrations of testosterone, luteinizing hormone, follicle stimulating hormone, prolactin, or cortisol (Block et al., 1991). Additionally, chronic marijuana use did not affect serum levels of thyrotropin, thyroxine, and triiodothyronine (Bonnet, 2013). However, in a double-blind, placebo-controlled, randomized clinical trial of HIV-positive men, smoking marijuana dose-dependently increased plasma levels of ghrelin and leptin, and decreased plasma levels of peptide YY (Riggs et al., 2012).

The effects of marijuana on female reproductive system functionality differ between humans and animals. In monkeys, delta^9-THC administration suppressed ovulation (Asch et al., 1981) and reduced progesterone levels (Almirez et al., 1983). However, in women, smoked marijuana did not alter hormone levels or the menstrual cycle (Mendelson and Mello, 1984). Brown and Dobs (2002) suggest that the development of tolerance in humans may be the cause of the discrepancies between animal and human hormonal response to cannabinoids.

The presence of *in vitro* delta^9-THC reduces binding of the corticosteroid, dexamethasone, in hippocampal tissue from adrenalectomized rats, suggesting an interaction with the glucocorticoid receptor (Eldridge et al., 1991). Although acute delta^9-THC presence releases corticosterone, tolerance develops in rats with chronic administration (Eldridge et al., 1991).

Some studies support a possible association between frequent, long-term marijuana use and increased risk of testicular germ cell tumors (Trabert et al., 2011). On the other hand, recent data suggest that cannabinoid agonists may have therapeutic value in the treatment of prostate cancer, a type of carcinoma in which growth is stimulated by androgens. Research with prostate cancer cells shows that the mixed CB_1/CB_2 agonist, WIN–55212–2, induces apoptosis in prostate cancer cells, as well as decreases the expression of androgen receptors and prostate-specific antigens (Sarfaraz et al., 2005).

Immune System

Cannabinoids affect the immune system in many different ways. Synthetic, natural, and endogenous cannabinoids often cause different effects in a dose-dependent biphasic manner (Croxford and Yamamura, 2005; Tanasescu and Constantinescu, 2010).

Studies in humans and animals give conflicting results about cannabinoid effects on immune functioning in subjects with compromised immune systems. Abrams et al. (2003) investigated marijuana's effect on immunological functioning in 62 AIDS patients taking protease inhibitors. Subjects received one of the following three times a day: A smoked marijuana cigarette containing 3.95 percent delta^9-THC, an oral tablet containing delta^9-THC (2.5 mg oral dronabinol), or an oral placebo. The results showed no changes in CD4+ and CD8+ cell counts, HIV RNA levels, or protease inhibitor levels between groups. Thus, the use of cannabinoids showed no short-term adverse virologic effects in individuals with compromised immune systems. However, these human data contrast with data generated in immunodeficient mice, which demonstrated that exposure to delta^9-THC *in vivo* suppresses immune function, increases HIV co-receptor expression, and acts as a cofactor to enhance HIV replication (Roth et al., 2005).

3. The State of Current Scientific Knowledge Regarding the Drug or Other Substance

Under the third factor, the Secretary must consider the state of current scientific knowledge regarding marijuana. Thus, this section discusses the chemistry, human pharmacokinetics, and medical uses of marijuana.

Chemistry

Marijuana is one of the common names of *Cannabis sativa* L. in the family Cannabaceae. *Cannabis* is one of the oldest cultivated crops, providing a source of fiber, food, oil, and drug. Botanists still debate whether *Cannabis* should be considered as a single (The Plant List, 2010) or three species, *i.e.,* C. *sativa,* C. *indica,* and C. *ruderalis* (Hillig, 2005). Specifically, marijuana is developed as sativa and indica cultivated varieties (strains) or various hybrids.

The petition defines marijuana as including all *Cannabis* cultivated strains. Different marijuana samples derived from various cultivated strains may have very different chemical constituents including delta^9 -THC and other cannabinoids (Appendino et al., 2011). As a consequence, marijuana products from different strains will have different safety, biological, pharmacological, and toxicological profiles. Thus, all *Cannabis* strains cannot be considered together because of the varying chemical constituents between strains.

Marijuana contains numerous naturally occurring constituents including cannabinoids. Overall, various *Cannabis* strains contain more than 525 identified natural constituents. Among those constituents, the most important ones are the 21 (or 22) carbon terpenoids found in the plant, as well as their carboxylic acids, analogues, and transformation products, known as cannabinoids (Agurell et al., 1984, 1986; Mechoulam, 1973; Appendino et al., 2011). Thus far, more than 100 compounds classified as cannabinoids have been characterized (ElSohly and Slade, 2005; Radwan, ElSohly et al., 2009; Appendino et al. 2011).

Cannabinoids primarily exist in *Cannabis,* and published data suggest that most major cannabinoid compounds occurring naturally have been chemically identified. New and minor cannabinoids and other new compounds are continuously being characterized (Pollastro et al., 2011). So far, only two cannabinoids (cannabigerol and its corresponding acid) have been obtained from a *non-Cannabis* source. A South African *Helichrysum (H umbraculigerum)* accumulates these compounds (Appendino et al. 2011).

Among the cannabinoids found in marijuana, delta^9-THC (alternate name delta^1-THC) and delta-8-tetrahydrocannibinol (delta^8-THC, alternate name delta^6-THC) produce marijuana's characteristic psychoactive effects. Because delta^9-THC is more abundant than delta^8-THC, marijuana's psychoactivity is largely attributed to the former. Only a few varieties of marijuana analyzed contain delta^8-THC at significant amounts (Hively et al., 1966). Delta^9-THC is an optically active resinous substance, insoluble in water, and extremely lipid soluble. Chemically, delta^9-THC is (6aR-trans)-6a,7,8,10a-tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo-[b,d]pyran-l-ol, or (−)-delta^9-(trans)-tetrahydrocannabinol. The (−)-trans isomer of delta^9-THC is pharmacologically 6–100 times more potent than the (+)-trans isomer (Dewey et al., 1984).

Other cannabinoids present in marijuana include CBD, CBC, and CBN. CBD, a major cannabinoid of marijuana, is insoluble in water and lipid-soluble. Chemically, CBD is 2-[(1R,6R)-3-methyl-6-prop-1-en-2-ylcyclohex-2-en-1-yl]-5-pentylbenzene-1,3-diol. CBD does not have cannabinol-like psychoactivity (Adams and Martin, 1996; Agurell et al., 1984, 1986; Hollister, 1986). CBC is another major cannabinoid in marijuana. Chemically, CBC is 2-methyl-2-(4-methylpent-3-enyl)-7-pentyl-5-chromenol. CBN, a major metabolite of delta^9-THC, is also a minor naturally-occurring cannabinoid with weak psychoactivity. Chemically, CBN is 6,6,9-trimethyl-3-pentylbenzo[c]chromen-1-ol.

Different marijuana samples derived from various cultivated strains may differ in chemical constituents including delta^9-THC and other cannabinoids (Appendino et al. 2011). As a consequence, marijuana products from different strains may have different safety, biological, pharmacological, and toxicological profiles. In addition to differences between cultivated strains, the concentration of delta^9-THC and other cannabinoids in marijuana may vary with growing conditions and processing after harvest. In addition to genetic differences among *Cannabis* species, the plant parts collected—for example, flowers, leaves, and stems—can influence marijuana's potency, quality, and purity (Adams and Martin, 1996; Agurell et al., 1984; Mechoulam, 1973). All these variations produce marijuana with potencies, as indicated by cannabinoid content, on average from as low as 1–2 percent to as high as 17 percent.

Overall, these variations in the concentrations of cannabinoids and other chemical constituents in marijuana complicate the interpretation of clinical data using marijuana. The lack of consistent concentrations of delta^9-THC and other substances in marijuana from diverse sources makes interpreting the effect of different marijuana constituents difficult. In addition to different cannabinoid concentrations having different pharmacological and toxicological profiles, the non-cannabinoid components in marijuana, such as other terpenoids and flavonoids, might also contribute to the overall pharmacological and toxicological profiles of various marijuana strains and products derived from those strains.

The term marijuana is often used to refer to a mixture of the dried flowering tops and leaves from *Cannabis.* Marijuana in this limiting definition is one of three major derivatives sold as separate illicit products, which also include hashish and hash oil. According to the DEA, *Cannabis saliva* is the primary species of *Cannabis* currently marketed illegally in the United States.

Marijuana can vary in cannabinoid content and potency (Agurell et al., 1984, 1986; Mechoulam 1973, Cascini et al., 2012). In the usual mixture of leaves and stems distributed as marijuana, the concentration of delta^9-THC averages over 12 percent by weight. However, specially grown and selected marijuana can contain 15 percent or greater delta^9-THC (Appendino et al. 2011). Thus, a 1-gram marijuana cigarette might contain delta^9-THC in a range from as little as 3 milligrams to as much as 150 milligrams or more. Additionally, a recent systematic review and meta-analysis found that marijuana's delta^9-THC content has increased significantly from 1979–2009 (Cascini et al., 2012). In addition to smoking marijuana, individuals ingest marijuana through food made with butter or oil infused with marijuana and its extracts. These marijuana butters are generally made by adding marijuana to butter and heating it. The resultant butter is then used to cook a variety of foods. There are no published studies measuring the concentrations of cannabinoids in these marijuana food products.

Hashish consists of the dried and compressed cannabinoid-rich resinous material of *Cannabis* and comes in a variety of forms (*e.g.* balls and cakes). Individuals may break off pieces, place it into a pipe and smoke it. DEA reports that cannabinoid content in hashish averages six percent (DEA, 2005). With the development and cultivation of more high potency *Cannabis* strains, the average cannabinoid content in hashish will likely increase.

Hash oil is produced by solvent extraction of the cannabinoids from plant material. The extract's color and odor vary, depending on the solvent type used. Hash oil is a viscous brown- or amber-colored liquid containing approximately 50 percent cannabinoids. One or two drops of the liquid placed on a cigarette purportedly produce the equivalent of a single· marijuana cigarette (DEA, 2005).

In conclusion, marijuana has hundreds of cultivars containing variable concentrations of delta^9-THC, cannabinoids, and other compounds. Thus, marijuana is not a single chemical with a consistent and reproducible chemical profile or predictable and consistent clinical effects. A guidance for industry, entitled *Botanical Drug Products,*[8] provides information on the approval of botanical drug products. To investigate marijuana for medical use in a manner acceptable as support for marketing approval under an NDA, clinical studies under an IND of consistent batches of a particular marijuana product for particular disease indications should be conducted. In addition, information and data regarding the marijuana product's chemistry, manufacturing and control, pharmacology, and animal toxicology data, among others must be provided and meet the requirements for new drug approval (See 21 CFR 314.50).

Human Pharmacokinetics

Marijuana can be taken in a variety of formulations by multiple routes of administration. Individuals smoke marijuana as a cigarette, weighing between 0.5 and 1.0 gram, or in a pipe. Additionally, individuals take marijuana orally in foods or as an extract in ethanol or other solvents. More recently, access to vaporizers provides another means for abusers to inhale marijuana,

The absorption, metabolism, and pharmacokinetic profile of delta^9-THC, cannabinoids, and drug products containing delta^9-THC vary with route of administratfon and formulation (Adams and Martin, 1996; Agurell et al., 1984, 1986).

Pharmacokinetics of Smoked Administration of Cannabinoids

Characterization of the pharmacokinetics of delta^9-THC and other cannabinoids from smoked marijuana is difficult because a subject's smoking behavior during an experiment varies (Agurell et al., 1986; Heming et al., 1986; Huestis et al., 1992a). Each puff delivers a discrete dose of delta^9-THC. An experienced marijuana smoker can titrate and regulate the dose to obtain the desired acute psychological effects and minimize undesired effects. For example, under naturalistic conditions, users hold marijuana smoke in their lungs for an extended period of time which causes prolonged absorption and increases psychoactive effects. The effect of experience in the psychological response may explain why delta^9-THC venous blood levels correlate poorly with intensity of effects and intoxication level (Agurell et al. 1986; Barnett et al. 1985; Huestis et al., 1992a). Puff and inhalation volumes should be recorded in studies as the concentration (dose) of cannabinoids administered can vary at different stages of smoking.

Smoked marijuana results in absorption of delta^9-THC in the form of an aerosol within seconds. Psychoactive effects occur immediately following absorption, with mental and behavioral effects measurable for up to 6 hours (Grotenhermen, 2003; Hollister 1986, 1988). Delta^9-THC is delivered to the brain rapidly and efficiently as expected of a very lipid soluble drug.

The bioavailability of the delta^9 -THC, from marijuana in a cigarette or pipe, can range from 1 to 24 percent with the fraction absorbed rarely exceeding 10 to 20 percent (Agurell et al.,1986; Hollister, 1988). The relatively low and variable bioavailability results from significant loss of delta^9-THC in side-stream smoke, variation in individual smoking behaviors, cannabinoid pyrolysis, incomplete absorption of inhaled smoke, and metabolism in the lungs. An individual's experience and technique with smoking marijuana also determines the dose absorbed (Heming et al., 1986; Johansson et al., 1989). After smoking, delta^9-THC venous levels decline precipitously within minutes, and continue to go down to about 5 to 10 percent of the peak level within an hour (Agurell et al., 1986, Huestis et al.,1992a, 1992b).

Pharmacokinetics for Oral Administration of Cannabinoids

After oral administration of delta^9-THC or marijuana, the onset of effects starts within 30 to 90 minutes, reaches its peak after 2 to 3 hours and then remains for 4 to 12 hours (Grotenhermen, 2003; Adams and Martin, 1996; Agurell et al., 1984, 1986). Due to the delay in onset of effects, users have difficulty in titrating oral delta^9-THC doses compared to smoking marijuana. Oral bioavailability of delta^9-THC, whether pure or in marijuana, is low and extremely variable, ranging between 5 and 20 percent (Agurell et al., 1984, 1986). Following oral administration of radioactive-labeled delta^9-THC, delta^9-THC plasma levels are low relative to plasma levels after smoking or intravenous administration. Inter- and intra-subject variability occurs even with repeated dosing under controlled conditions. The low and variable oral bioavailability of delta^9-THC is a consequence of its first-pass hepatic elimination from blood and erratic absorption from stomach and bowel.

Cannabinoid Metabolism and Excretion

Cannabinoid metabolism is complex. Delta^9-THC is metabolized via microsomal hydroxylation to both active and inactive metabolites (Lemberger et al., 1970, 1972a, 1972b; Agurell et al., 1986; Hollister, 1988). The primary active metabolite of delta^9-THC following oral ingestion is 11-hydroxy-delta^9-THC. This metabolite is approximately equipotent to delta^9-THC in producing marijuana-like subjective effects (Agurell et al., 1986, Lemberger and Rubin, 1975). After oral administration, metabolite levels may exceed that of delta^9-THC and thus contribute greatly to the pharmacological effects of oral delta^9-THC or marijuana.

Plasma clearance of delta^9-THC approximates hepatic blood flow at about 950 ml/min or greater. The rapid disappearance of delta^9-THC from blood is largely due to redistribution to other tissues in the body, rather than to metabolism (Agurell et al., 1984, 1986). Metabolism in most tissues is relatively slow or absent. Slow release of delta^9-THC and other cannabinoids from tissues and subsequent metabolism results in a long elimination half-life. The terminal half-life of delta^9-THC ranges from approximately 20 hours to as long as 10 to13 days, though reported estimates vary as expected with any slowly cleared substance and the use of assays with variable sensitivities (Hunt and Jones, 1980). Lemberger et al. (1970) determined the half-life of delta^9-THC to range from 23 to 28 hours in heavy marijuana users to 60 to 70 hours in naive users. In addition to 11-hydroxy-delta^9-THC, some inactive carboxy metabolites have terminal half-lives of 50 hours to 6 days or more. The latter substances serve as long-term markers in urine tests for earlier marijuana use.

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[8] This guidance is available on the Internet at *http://www.fda.gov/Drugs/default.htm* under Guidance (Drugs).

The majority of the absorbed delta^9-THC dose is eliminated in feces, and about 33 percent in urine. Delta^9-THC enters enterohepatic circulation and undergoes hydroxylation and oxidation to 11-nor-9-carboxy-delta^9-THC. The glucuronide is excreted as the major urine metabolite along with about 18 non-conjugated metabolites. Frequent and infrequent marijuana users metabolize delta^9-THC similarly (Agurell et al., 1986).

Status of Research Into the Medical Uses for Marijuana

State-level public initiatives, including laws and referenda in support of the medical use of marijuana, have generated interest in the medical community and the need for high quality clinical investigation as well as comprehensive safety and effectiveness data. In order to address the need for high quality clinical investigations, the state of California established the Center for Medicinal Cannabis Research (CMCR, *www.cmcr.ucsd.edu*) in 2000 "in response to scientific evidence for therapeutic possibilities of cannabis [9] and local legislative initiatives in favor of compassionate use" (Grant, 2005). State legislation establishing the CMCR called for high quality medical research that would "enhance understanding of the efficacy and adverse effects of marijuana as a pharmacological agent," but stressed the project "should not be construed as encouraging or sanctioning the social or recreational use of marijuana." The CMCR funded many of the published studies on marijuana's potential use for treating multiple sclerosis, neuropathic pain, appetite suppression and cachexia. However, aside from the data produced by CMCR, no state-level medical marijuana laws have produced scientific data on marijuana's safety and effectiveness.

FDA approves medical use of a drug following a submission and review of an NDA or BLA. The FDA has not approved any drug product containing marijuana for marketing. Even so, results of small clinical exploratory studies have been published in the current medical literature. Many studies describe human research with marijuana in the United States under FDA-regulated IND applications.

However, FDA approval of an NDA is not the only means through which a drug can have a currently accepted medical use in treatment in the United States. In general, a drug may have a "currently accepted medical use" in treatment in the United States if the drug meets a five-part test. Established case law (Alliance for Cannabis Therapeutics v. DEA, 15 F.3d 1131, 1135 (D.C. Cir. 1994)) upheld the Administrator of DEA's application of the five-part test to determine whether a drug has a "currently accepted medical use." The following describes the five elements that characterize "currently accepted medical use" for a drug: [10]

i. the drug's chemistry must be known and reproducible

"The substance's chemistry must be scientifically established to permit it to be reproduced into dosages which can be standardized. The listing of the substance in a current edition of one of the official compendia, as defined by section 201 G) of the Food, Drug and Cosmetic Act, 21 U.S.C. 321G), is sufficient to meet this requirement."

ii. there must be adequate safety studies

"There must be adequate pharmacological and toxicological studies, done by all methods reasonably applicable, on the basis of which it could fairly and responsibly be concluded, by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, that the substance is safe for treating a specific, recognized disorder."

iii. there must be adequate and well-controlled studies proving efficacy

"There must be adequate, well-controlled, well-designed, well-conducted, and well-documented studies, including clinical investigations, by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, on the basis of which it could be fairly and responsibly concluded by such experts that the substance will have the intended effect in treating a specific, recognized disorder."

iv. the drug must be accepted by qualified experts

"The drug has a New Drug Application (NDA) approved by the Food and Drug Administration, pursuant to the Food, Drug and Cosmetic Act, 21 U.S.C. 355. Or, a consensus of the national community of experts, qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, accepts the safety and effectiveness of the substance for use in treating a specific, recognized disorder. A material conflict of opinion among experts precludes a finding of consensus." and

v. the scientific evidence must be widely available

"In the absence of NDA approval, information concerning the chemistry, pharmacology, toxicology, and effectiveness of the substance must be reported, published, or otherwise widely available, in sufficient detail to permit experts, qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, to fairly and responsibly conclude the substance is safe and effective for use in treating a specific, recognized disorder."

Marijuana does not meet any of the five elements necessary for a drug to have a "currently accepted medical use."

Firstly, the chemistry of marijuana, as defined in the petition, is not reproducible in terms of creating a standardized dose. The petition defines marijuana as including all *Cannabis* cultivated strains. Different marijuana samples derived from various cultivated strains may have very different chemical constituents including delta9–THC and other cannabinoids (Appendino et al., 2011). As a consequence, marijuana products from different strains will have different safety, biological, pharmacological, and toxicological profiles. Thus, when considering all *Cannabis* strains together, because of the varying chemical constituents, reproducing consistent standardized doses is not possible. Additionally, smoking marijuana currently has not been shown to allow delivery of consistent and reproducible doses. However, if a specific *Cannabis* strain is grown and processed under strictly controlled conditions, the plant chemistry may be kept consistent enough to produce reproducible and standardized doses.

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[9] In this quotation the term cannabis is interchangeable with marijuana.

[10] 57 FR I 0499, 10504–06 (March 26, 1992).

As to the second and third criteria; there are neither adequate safety studies nor adequate and well-controlled studies proving marijuana's efficacy. To support the petitioners' assertion that marijuana has accepted medical use, the petitioners cite the American Medical Association's (AMA) 2009 report entitled "Use of Cannabis for Medicinal Purposes." The petitioners claim the AMA report is evidence the AMA accepts marijuana's safety and efficacy. However, the 2009 AMA report clarifies that the report "should not be viewed as an endorsement of state-based medical cannabis programs, the legalization of marijuana, or that scientific evidence on the therapeutic use of cannabis meets the same and current standards for a prescription drug product." [11]

Currently, no published studies conducted with marijuana meet the criteria of an adequate and well-controlled efficacy study. The criteria for an adequate and well-controlled study for purposes of determining the safety and efficacy of a human drug are defined under the Code of Federal Regulations (CFR) in 21 CFR 314.126. In order to assess this element, FDA conducted a review of clinical studies published and available in the public domain before February, 2013. Studies were identified through a search of PubMed [12] for articles published from inception to February 2013, for randomized controlled trials using marijuana to assess marijuana's efficacy in any therapeutic indication. Additionally, the review included studies identified through a search of bibliographic references in relevant systematic reviews and identified studies presenting original research in any language. Selected studies needed to be placebo-controlled and double-blinded. Additionally, studies needed to encompass administered marijuana plant material. There was no requirement for any specific route of administration, nor any age limits on study subjects. Studies were excluded that used placebo marijuana supplemented by the addition of specific amounts of THC or other cannabinoids. Additionally, studies administering marijuana plant extracts were excluded.

The PubMed search yielded a total of 566 abstracts of scientific articles. Of these abstracts, a full-text review was conducted with 85 papers to assess eligibility. Of the studies identified through the search of the references and the 566 abstracts from the PubMed search, only 11 studies met all the criteria for selection (Abrams et al., 2007; Corey-Bloom et al., 2012; Crawford and Merritt, 1979; Ellis et al., 2009; Haney et al., 2005; Haney et al., 2007; Merritt et al., 1980; Tashkin et al., 1974; Ware et al., 2010; Wilsey et al., 2008; Wilsey et al., 2013). These 11 studies were published between 197 4 and 2013. Ten of these studies were conducted in the United States and one study was conducted in Canada. The identified studies examine the effects of smoked and vaporized marijuana for the indications of chronic neuropathic pain, spasticity related to Multiple Sclerosis (MS), appetite stimulation in human immunodeficiency virus (HIV) patients, glaucoma, and asthma. All studies used adult subjects.

The 11 identified studies were individually evaluated to determine if they successfully meet accepted scientific standards. Specifically, they were evaluated on study design including subject selection criteria, sample size, blinding techniques, dosing paradigms, outcome measures, and the statistical analysis of the results. The analysis relied on published studies, thus information available about protocols, procedures, and results were limited to documents published and widely available in the public domain. The review found that all 11 studies that examined effects of inhaled marijuana do not currently prove efficacy of marijuana in any therapeutic indication based on a number of limitations in their study design; however, they may be considered proof of concept studies. Proof of concept studies provide preliminary evidence on a proposed hypothesis involving a drug's effect. For drugs under development, the effect often relates to a short-term clinical outcome being investigated. Proof of concept studies often serve as the link between preclinical studies and dose ranging clinical studies. Thus, proof of concept studies generally are not sufficient to prove efficacy of a drug because they provide only preliminary information about the effects of a drug.

In addition to the lack of published adequate and well-controlled efficacy studies proving efficacy, the criteria for adequate safety studies has also not been met. Importantly, in its discussion of the five-part test used to determine whether a drug has a "currently accepted medical use," DEA said, "No drug can be considered safe in the abstract. Safety has meaning only when judged against the intended use of the drug, its known effectiveness, its known and potential risks, the severity of the illness to be treated, and the availability of alternative remedies" (57 FR 10504). When determining whether a drug product is safe and effective for any indication, FDA performs an extensive risk-benefit analysis to determine whether the risks posed by the drug product's side effects are outweighed by the drug product's potential benefits for a particular indication. Thus, contrary to the petitioner's assertion that marijuana has accepted safety, in the absence of an accepted therapeutic indication which can be weighed against marijuana's risks, marijuana does not satisfy the element for having adequate safety studies such that experts may conclude that it is safe for treating a specific, recognized disorder.

The fourth of the five elements for determining "currently accepted medical use" requires that the national community of experts, qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, accepts the safety and effectiveness of the substance for use in treating a specific, recognized disorder. A material conflict of opinion among experts precludes a finding of consensus. Medical practitioners who are not experts in evaluating drugs are not qualified to determine whether a drug is generally recognized as safe and effective or meets NDA requirements (57 FR 10499–10505).

There is no evidence that there is a consensus among qualified experts that marijuana is safe and effective for use in treating a specific, recognized disorder. As discussed above, there are not adequate scientific studies that show marijuana is safe and effective in treating a specific, recognized disorder. In addition, there is no evidence that a consensus of qualified experts have accepted the safety and effectiveness of marijuana for use in treating a specific, recognized disorder. Although medical practitioners are not qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, we also note that the AMA's report, entitled "Use of Cannabis for Medicinal Purposes," does not accept that marijuana currently has accepted medical use. Furthermore, based on the above definition of a "qualified expert", who is an individual qualified by scientific training and experience to evaluate the safety and effectiveness of a drug, state-level medical marijuana laws do not provide evidence of a consensus among qualified experts that marijuana is safe and effective for use in treating a specific, recognized disorder.

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[11] In this quotation the term cannabis is used interchangeably for marijuana.

[12] The following search strategy was used, "(cannabis OR marijuana) AND (therapeutic use OR therapy) AND (RCT OR randomized controlled trial OR "systematic review" OR clinical trial OR clinical trials) NOT ("marijuana abuse"[Mesh] OR addictive behavior OR substance related disorders)."

As to the fifth part of the test, which requires that information concerning the chemistry, pharmacology, toxicology, and effectiveness of marijuana to be reported in sufficient detail, the scientific evidence regarding all of these aspects is not available in sufficient detail to allow adequate scientific scrutiny. Specifically, the scientific evidence regarding marijuana's chemistry in terms of a specific *Cannabis* strain that could produce standardized and reproducible doses is not currently available.

Alternately, a drug can be considered to have a "currently accepted medical use with severe restrictions" (21 U.S.C. 812(b)(2)(B)), as allowed under the stipulations for a Schedule II drug. Yet, as stated above, currently marijuana does not have any accepted medical use, even under conditions where its use is severely restricted.

In conclusion, to date, research on marijuana's medical use has not progressed to the point where marijuana is considered to have a "currently accepted medical use" or a "currently accepted medical use with severe restrictions."

4. Its History and Current Pattern of Abuse

Under the fourth factor, the Secretary must consider the history and current pattern of marijuana abuse. A variety of sources provide data necessary to assess abuse patterns and trends of marijuana. The data indicators of marijuana use include the NSDUH, MTF, DAWN, and TEDS. The following briefly describes each data source, and summarizes the data from each source.

National Survey on Drug Use and Health (NSDUH)[13]

According to 2012 NSDUH[14] data, the most recent year with complete data, the use of illicit drugs, including marijuana, is increasing. The 2012 NSDUH estimates that 23.9 million individuals over 12 years of age (9.2 percent of the U.S. population) currently use illicit drugs, which is an increase of 4.8 million individuals from 2004 when 19.1 million individuals (7.9 percent of the U.S. population) were current illicit drug users. NSDUH reports marijuana as the most commonly used illicit drug, with 18.9 million individuals (7.3 percent of the U.S. population) currently using marijuana in 2012. This represents an increase of 4.3 million individuals from 2004, when 14.6 million individuals (6.1 percent of the U.S. population) were current marijuana users.

The majority of individuals who try marijuana at least once in their lifetime do not currently use marijuana. The 2012 NSDUH estimates that 111.2 million individuals (42.8 percent of the U.S. population) have used marijuana at least once in their lifetime. Based on this estimate and the estimate for the number of individuals currently using marijuana, approximately 16.9 percent of those who have tried marijuana at least once in their lifetime currently use marijuana; conversely, 83.1 percent do not currently use marijuana. In terms of the frequency of marijuana use, an estimated 40.3 percent of individuals who used marijuana in the past month used marijuana on 20 or more days within the past month. This amount corresponds to an estimated 7.6 million individuals who used marijuana on a daily or almost daily basis.

Some characteristics of marijuana users are related to age, gender, and criminal justice system involvement. In observing use among different age cohorts, the majority of individuals who currently use marijuana are shown to be between the ages of 18–25, with 18.7 percent of this age group currently using marijuana. In the 26 and older age group, 5.3 percent of individuals currently use marijuana. Additionally, in individuals aged 12 years and older, males reported more current marijuana use than females.

NSDUH includes a series of questions aimed at assessing the prevalence of dependence and abuse of different substances in the past 12 months.[15] In 2012, marijuana was the most common illicit drug reported by individuals with past year dependence or abuse. An estimated 4.3 million individuals meet the NSDUH criteria for marijuana dependence or abuse in 2012. The estimated rates and number of individuals with marijuana dependence or abuse has remained similar from 2002 to 2012. In addition to data on dependence and abuse, NSDUH includes questions aimed at assessing treatment for a substance use problem.[16] In 2012, an estimated 957,000 persons received treatment for marijuana use during their most recent treatment in the year prior to the survey.

Monitoring the Future (MTF)[17]

According to MTF,[18] rates of marijuana and illicit drug use declined for all three grades from 2005 through 2007. However, starting around 2008, rates of annual use of illicit drugs and marijuana increased through 2013 for all three grades. Marijuana remained the most widely used illicit drug during all time periods. The prevalence of annual and past month marijuana use in 10th and 12th graders in 2013 is greater than in 2005. Table 1 lists the lifetime, annual, and monthly prevalence rates of various drugs for 8th, 10th, and 12th graders in 2013.

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[13] NSDUH provides national estimates of the prevalence and incidence of illicit drug, alcohol and tobacco use in the United States. NSDUH is an annual study conducted by SAMHSA. Prior to 2002, the database was known as the National Household Survey on Drug Abuse (NHSDA). NSDUH utilizes a nationally representative sample of United States civilian, non-institutionalized population aged 12 years and older. The survey excludes homeless people who do not use shelters, active military personnel, and residents of institutional group quarters such as jails and hospitals. The survey identifies whether an individual used a drug within a specific time period, but does not identify the amount of the drug used on each occasion. NSDUH defines "current use" as having used the substance within the month prior to the study.

[14] 2013; *http://www.samhsa.gov/data/NSDUH.aspx.*

[15] "These questions are used to classify persons as dependent on or abusing specific substances based on criteria specified in the *Diagnostic and Statistical Manual of Mental Disorder,* 4th edition (DSM–IV). The questions related to dependence ask about health and emotional problems associated with substance use, unsuccessful attempts to cut down on use, tolerance, withdrawal, reducing other activities to use substances, spending a lot time engaging in activities related to substance use, or using the substance in greater quantities or for longer time than intended. The questions on abuse ask about problems at work, home, and school; problems with family or friends; physical danger; and trouble with the law due to substance use. Dependence is considered to be a more severe substance use problem than abuse because it involves the psychological and physiological effects of tolerance and withdrawal." (NSDUH, 2013).

[16] "Estimates . . . refer to treatment received for illicit drug or alcohol use, or for medical problems associated with the use of illicit drugs or alcohol. This includes treatment received in the past year at any location, such as a hospital (inpatient), rehabilitation facility (outpatient or inpatient), mental health center, emergency room, private doctor's office, prison or jail, or a self-help group, such as Alcoholics Anonymous or Narcotics Anonymous." (NSDUH, 2013).

[17] Monitoring the Future is a national survey that tracks drug use prevalence and trends among adolescents in the United States. MTF is reported annually by the Institute for Social Research at the University of Michigan under a grant from NIDA. Every spring, MTF surveys 8th, 10th, and 12th graders in randomly selected U.S. schools. MTF has been conducted since 1975 for 12th graders and since 1991 for 8th and 10th graders. The MTF survey presents data in terms of prevalence among the sample interviewed. For 2012, the latest year with complete data, the sample sizes were 15,200—8th graders; 13,300—10th graders; and 13,200—12th graders. In all, a total of about 41,700 students of 389 schools participated in the 2013 MTF.

[18] 2013; *http://www.monitoringthefuture.org/index.html.*

Table 1: Trends in lifetime, annual, and monthly prevalence of use of various drugs for eighth, tenth, and twelfth graders. Percentages represent students in survey responding that they had used a drug at least once in their lifetime, in the past year, or in the past 30 days.

	Lifetime			Annual			30-Day		
	2011	2012	2013	2011	2012	2013	2011	2012	2013
Any illicit Drug (a)									
8th Grade	20.1	18.5	20.3	14.7	13.4	14.9	8.5	7.7	8.5
10th Grade	37.7	36.8	38.8	31.1	30.1	31.8	19.2	18.6	19.4
12th Grade	49.9	49.1	50.4	40.0	39.7	40.3	25.2	25.2	25.5
Marijuana/Hashish									
8th Grade	16.4	15.2	16.5	12.5	11.4	12.7	7.2	6.5	7.0
10th Grade	34.5	33.8	35.8	28.8	28.0	29.8	17.6	17.0	18.0
12th Grade	45.5	45.2	45.5	36.4	36.4	36.4	22.6	22.9	22.7

SOURCE: The Monitoring the Future Study, the University of Michigan
a. For 12th graders only: "any illicit drug" includes any use of marijuana, LSD, other hallucinogens, crack, other cocaine, or heroin; or any narcotics use other than heroin, amphetamines, sedatives (barbiturates), or tranquilizers not under a doctor's orders. For 8th and 10th graders only: the use of narcotics other than heroin and sedatives (barbiturates) was excluded.

Drug Abuse Warning Network (DAWN) [19]

Importantly, many factors can influence the estimates of ED visits, including trends in overall use of a substance as well as trends in the reasons for ED usage. For instance, some drug users may visit EDs for life-threatening issues while others may visit to seek care for detoxification because they needed certification before entering treatment. Additionally, DAWN data do not distinguish the drug responsible for the ED visit from other drugs that may have been used concomitantly. As stated in a DAWN report, "Since marijuana/hashish is frequently present in combination with other drugs, the reason for the ED visit may be more relevant to the other drug(s) involved in the episode."

For 2011, DAWN [20] estimates a total of 5,067,374 (95 percent confidence interval [CI]: 4,616,753 to 5,517,995) drug-related ED visits from the entire United States. Of these, approximately 2,462,948 ([CI]: 2,112,868 to 2,813,028) visits involved drug misuse or abuse.

During the same period, DAWN estimates that 1,252,500 (CI: 976,169 to 1,528,831) drug related ED visits involved illicit drugs. Thus, over half of all drug-related ED visits associated with drug misuse or abuse involved an illicit drug. For ED visits involving illicit drugs, 56.3 percent involved multiple drugs while 43.7 percent involved a single drug.

Marijuana was involved in 455,668 ED visits (CI: 370,995 to 540,340), while cocaine was involved in 505,224 (CI: 324,262 to 686,185) ED visits, heroin was involved in 258,482 (CI: 205,046 to 311,918) ED visits and stimulants including amphetamine and methamphetamine were involved in 159,840 (CI: 100,199 to 219,481) ED visits. Other illicit drugs, such as PCP, MDMA, GHB and LSD were much less frequently associated with ED visits. The number of ED visits involving marijuana has increased by 62 percent since 2004.

Marijuana-related ED visits were most frequent among young adults and minors. Individuals under the age of 18 accounted for 13.2 percent of these marijuana-related visits, whereas this age group accounted for approximately 1.2 percent of ED visits involving cocaine, and less than 1 percent of ED visits involving heroin. However, the age group with the most marijuana-related ED visits was between 25 and 29 years old. Yet, because populations differ between age groups, a standardized measure for population size is useful to make comparisons. For marijuana, the rates of ED visits per 100,000 population were highest for patients aged 18 to 20 (443.8 ED visits per 100,000) and for patients aged 21 to 24 (446.9 ED visits per 100,000).

While DAWN provides estimates for ED visits associated with the use of medical marijuana for 2009–2011, the validity of these estimates is questionable. Because the drug is not approved by the FDA, reporting medical marijuana may be inconsistent and reliant on a number of factors including whether the patient self-reports the marijuana use as medicinal, how the treating health care provider records the marijuana use, and lastly how the SAMHSA coder interprets the report. All of these aspects will vary greatly between states with medical marijuana laws and states without medical marijuana laws. Thus, even though estimates are reported for medical marijuana related ED visits, medical marijuana estimates cannot be assessed with any acceptable accuracy at this time, as FDA has not approved marijuana treatment of any medical condition. These data show the difficulty in evaluating abuse of a product that is not currently approved by FDA, but authorized for medical use, albeit inconsistently, at the state level. Thus, we believe the likelihood of the treating health care provider or SAMHSA coder attributing the ED visit to "medical marijuana" versus "marijuana" to be very low. Overall, the available data are inadequate to characterize its abuse at the community level.

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[19] DAWN is a national probability survey of the U.S. hospitals with ED designed to obtain information on drug related ED visits. DAWN is sponsored by SAMHSA. The DAWN system provides information on the health consequences of drug use in the United States, as manifested by drug-related visits to ED. The ED data from a representative sample of hospital emergency departments are weighted to produce national estimates. Importantly, DAWN data and estimates, starting in 2004, are not comparable to those for prior years because of vast changes in the methodology used to collect the data. Furthermore, estimates for 2004 are the first to be based on a redesigned sample of hospitals, which ended in 2011.

[20] 2011; *http://www.samhsa.gov/data/dawn.aspx.*

Treatment Episode Data Set (TEDS)[21]

Primary marijuana abuse accounted for 18.1 percent of all 2011 TEDS[22] admissions. Individuals admitted for primary marijuana abuse were nearly three-quarters (73.4 percent) male, and almost half (45.2 percent) were white. The average age at admission was 24 years old, and 31.1 percent of individuals admitted for primary marijuana abuse were under the age of 18. The reported frequency of marijuana use was 24.3 percent reporting daily use. Almost all (96.8 percent) primary marijuana users utilized the substance by smoking. Additionally, 92.9 percent reported using marijuana for the first time before the age of 18.

An important aspect of TEDS admission data for marijuana is of the referral source for treatment. Specifically, primary marijuana admissions were less likely than all other admissions to either be self-referred or referred by an individual for treatment. Instead, the criminal justice system referred more than half (51.6 percent) of primary marijuana admissions.

Since 2003, the percent of admissions for primary marijuana abuse increased from 15.5 percent of all admissions in 2003 to 18.1 percent in 2011. This increase is less than the increase seen for admissions for primary opioids other than heroin, which increased from 2.8 percent in 2003 to 7.3 percent in 2011. In contrast, the admissions for primary cocaine abuse declined from 9.8 percent in 2003 to 2.0 percent in 2011.

5. The Scope, Duration, and Significance of Abuse

Under the fifth factor, the Secretary must consider the scope, duration, and significance of marijuana abuse. According to 2012 data from NSDUH and 2013 data from MTF, marijuana remains the most extensively used illegal drug in the United States, with 42.8 percent of U.S. individuals over age 12 (111.2 million) and 45.5 percent of 12th graders having used marijuana at least once in their lifetime. Although the majority of individuals over age 12 (83.1 percent) who have ever used marijuana in their lifetime do not use the drug monthly, 18.9 million individuals (7.3 percent of the U.S. population) report that they used marijuana within the past 30 days. An examination of use among various age cohorts through NSDUH demonstrates that monthly use occurs primarily among college-aged individuals, with use dropping off sharply after age 25. Additionally, NSDUH data show the number of individuals reporting past-month use of marijuana has increased by 4.3 million individuals since 2004. Data from MTF shows that annual prevalence of marijuana use declined for all three grades from 2005 through 2007, then began to rise through 2013. Additionally, in 2013, 1.1 percent of 8th graders, 4.0 percent of 10th graders, and 6.5 percent of 12th graders reported daily use of marijuana, defined as use on 20 or more days within the past 30 days.

The 2011 DAWN data show that marijuana use was mentioned in 455,668 ED visits, which amounts to approximately 36.4 percent of all illicit drug-related ED visits.[23]

TEDS data for 2011 show that 18.1 percent of all admissions were for primary marijuana abuse.[24] Between 2003 and 2011, there was a 2.6 percent increase in the number of TEDS admissions for primary marijuana use. Approximately 61.5 percent of primary marijuana admissions in 2011 were for individuals under the age of 25 years.

6. What, if Any, Risk There Is to the Public Health

Under the sixth factor, the Secretary must consider the risks posed to the public health by marijuana. Factors 1, 4, and 5 include a. discussion of the risk to the public health as measured by emergency room episodes and drug treatment admissions. Additionally, Factor 2 includes a discussion of marijuana's central nervous system, cognitive, cardiovascular, autonomic, respiratory, and immune system effects. Factor 6 focuses on the health risks to the individual user in terms of the risks from acute and chronic use of marijuana, as well as the "gateway hypothesis."

Risks From Acute Use of Marijuana

Acute use of marijuana impairs psychomotor performance, including complex task performance, which makes operating motor vehicles or heavy equipment after using marijuana inadvisable (Ramaekers et al., 2004; Ramaekers et al., 2006a). A meta-analysis conducted by Li et al. (2011) showed an association between marijuana use by the driver and a significantly increased risk of involvement in a car accident. Additionally, in a minority of individuals who use marijuana, some potential responses include dysphoria and psychological distress, including prolonged anxiety reactions (Haney et al., 1999).

Risks From Chronic Use of Marijuana

A distinctive marijuana withdrawal syndrome following long term or chronic use has been identified. The withdrawal syndrome indicates that marijuana produces physical dependence that is mild, short-lived, and comparable to tobacco withdrawal (Budney et al., 2008). Marijuana withdrawal syndrome is described in detail below under Factor 7.

The following states how the DSM–V (2013) of the American Psychiatric Association describes the consequences of *Cannabis*[25] abuse:

Individuals with cannabis use disorder may use cannabis throughout the day over a period of months or years, and thus may spend many hours a day under the influence. Others may use less frequently, but their use causes recurrent problems related to family, school, work, or other important activities (*e.g.,* repeated absences at work; neglect of family obligations). Periodic cannabis use and intoxication can negatively affect behavioral and cognitive functioning and thus interfere with optimal performance at work or school, or place the individual at increased physical risk when performing activities that could be physically hazardous (e.g:, driving a car; playing certain sports; performing manual work activities, including operating machinery). Arguments with spouses or parents over the use of cannabis in the home, or its use in the presence of children, can adversely impact family functioning and are common features of those with cannabis use disorder. Last, individuals with cannabis use disorder may continue using marijuana despite knowledge of physical problems (*e.g.,* chronic cough related to smoking) or psychological problems (*e.g.,* excessive sedation or exacerbation of other mental health problems) associated with its use.

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[21] The TEDS system is part of SAMHSA's Drug and Alcohol Services Information System (Office of Applied Science, SAMHSA). The TEDS report presents information on the demographic and substance use characteristics of the 1.8 million annual admissions to treatment for alcohol and drug abuse in facilities that report to individual state administrative data systems. Specifically, TEDS includes facilities licensed or certified by the states to provide substance abuse treatment and is required by the states to provide TEDS client-level data. Facilities that report TEDS data are those receiving State alcohol and drug agency funds for the provision of alcohol and drug treatment services. Since TEDS is based only on reports from these facilities, TEDS data do not represent the total national demand for substance abuse treatment or the prevalence of substance abuse in the general population. The primary goal for TEDS is to monitor the characteristics of treatment episodes for substance abusers. Importantly, TEDS is an admissions-based system, where admittance to treatment is counted as an anonymous tally. For instance, a given individual who is admitted to treatment twice within a given year would be counted as two admissions. The most recent year with complete data is 2011.

[22] 2011; *http://www.samhsa.gov/data/DASIS.aspx?qr=t#TEDS.*

[23] Many factors can influence the estimates of ED visits, including trends in the reasons for ED usage. For instance, some drug users may visit EDs for life-threatening issues while others may visit to seek care for detoxification because they needed certification before entering treatment. Additionally, DAWN data do not distinguish the drug responsible for the ED visit from other drugs that may have been used concomitantly. As stated in a DAWN report, "Since marijuana/hashish is frequently present in combination with other drugs, the reason for the ED visit may be more relevant to the other drug(s) involved in the episode."

[24] An important aspect of TEDS admission data for marijuana is of the referral source for treatment. Specifically, primary marijuana admissions were less likely than all other admissions to either be self-referred or referred by an individual for treatment. Instead, the criminal justice system referred more than half (51.6 percent) of primary marijuana admissions.

[25] *Cannabis* is the term used in the DSM–V to refer to marijuana. In the following excerpt the term *Cannabis* is interchangeable for the term *marijuana.*

Marijuana as a "Gateway Drug"

Kandel (1975) proposed nearly 40 years ago the hypothesis that marijuana is a "gateway drug" that leads to the use or abuse of other illicit drugs. Since that time, epidemiological research explored this premise. Overall, research does not support a direct causal relationship between regular marijuana use and other illicit drug use. The studies examining the gateway hypothesis are limited. First, in general, studies recruit individuals influenced by a myriad of social, biological, and economic factors that contribute to extensive drug abuse (Hall & Lynskey, 2005). Second, most studies that test the hypothesis that marijuana use causes abuse of illicit drugs use the determinative measure *any use of an illicit drug,* rather than DSM–5 criteria for drug abuse or dependence on an illicit drug (DSM–5, 2013). Consequently, although an individual who used marijuana may try other illicit drugs, the individual may not regularly use drugs, or have a diagnosis of drug abuse or dependence.

Little evidence supports the hypothesis that initiation of marijuana use leads to an abuse disorder with other illicit substances. For example, one longitudinal study of 708 adolescents demonstrated that early onset marijuana use did not lead to problematic drug use (Kandel & Chen, 2000). Similarly, Nace et al. (1975) examined Vietnam-era soldiers who extensively abused marijuana and heroin while they were in the military, and found a lack of correlation of a causal relationship demonstrating marijuana use leading to heroin addiction. Additionally, in another longitudinal study of 2,446 adolescents, marijuana dependence was uncommon but when it did occur, the common predictors of marijuana dependence were the following: parental death, deprived socio-economic status, and baseline illicit drug use other than marijuana (von Sydow et al., 2002).

When examining the association between marijuana and illicit drugs, focusing on drug use versus abuse or dependence, different patterns emerge. For example, a study examining the possible causal relationship of the gateway hypothesis found a correlation between marijuana use in adolescents and other illicit drug use in early adulthood and, adjusting for age-linked experiences, did not effect this correlation (Van Gundy and Rebellon, 2010). However, when examining the association in terms of development of drug abuse; age-linked stressors and social roles moderated the correlation between marijuana use in adolescents and other illicit drug abuse. Similarly, Degenhardt et al. (2009) examined the development of drug dependence and found an association that did not support the gateway hypothesis. Specifically, drug dependence was significantly associated with the use of other illicit drugs prior to marijuana use.

Interestingly, the order of initiation of drug use seems to depend on the prevalence of use of each drug, which varies by country. Based on the World Health Organization (WHO) World Mental Health Survey that includes data from 17 different countries, the order of drug use initiation varies by country and relates to prevalence of drug use in each country (Degenhardt et al., 2010). Specifically, in the countries with the lowest prevalence of marijuana use, use of other illicit drugs before marijuana was common. This sequence of initiation is less common in countries with higher prevalence of marijuana use. A study of 9,282·households in the United States found that marijuana use often preceded the use of other illicit drugs; however, prior non-marijuana drug dependence was also frequently correlated with higher levels of illicit drug abuse (Degenhardt et al., 2009). Additionally, in a large 25-year longitudinal study of 1,256 New Zealand children, the author concluded that marijuana use correlated to an increased risk of abuse of other drugs, including cocaine and heroin (Fergusson et al., 2005).

Although many individuals with a drug abuse disorder may have used marijuana as one of their first illicit drugs, this fact does not correctly lead to the reverse inference that most individuals who used marijuana will inherently go on to try or become regular users of other illicit drugs. Specifically, data from the 2011 NSDUH survey illustrates this issue (SAMHSA, 2012). NSDUH data estimates 107.8 million individuals have a lifetime history of marijuana use, which indicates use on at least one occasion, compared to approximately 36 million individuals having a lifetime history of cocaine use and approximately 4 million individuals having a lifetime history of heroin use. NSDUH data do not provide information about each individual's specific drug history. However, even if one posits that every cocaine and heroin user previously used marijuana, the NSDUH data show that marijuana use at least once in a lifetime does not predict that an individual will also use another illicit drug at least once.

Finally, a review of the gateway hypothesis by Vanyukov et al. (2012) notes that because the gateway hypothesis only addresses the order of drug use initiation, the gateway hypothesis does not specify any mechanistic connections between drug "stages" following exposure to marijuana and does not extend to the risks for addiction. This concept contrasts with the concept of a common liability to addiction that involves mechanisms and biobehavioral characteristics pertaining to the entire course of drug abuse risk and disorders.

7. Its Psychic or Physiologic Dependence Liability

Under the seventh factor, the Secretary must consider marijuana's psychic or physiological dependence liability.

Psychic or psychological dependence has been shown in response to marijuana's psychoactive effects. Psychoactive responses to marijuana are pleasurable to many humans and are associated with drug-seeking and drug-taking (Maldonado, 2002). Moreover, high levels of psychoactive effects, notably positive reinforcement, are associated with increased marijuana use, abuse, and dependence (Scherrer et al., 2009; Zeiger et al., 2010). Epidemiological data support these findings through 2012 NSDUH statistics that show that of individuals years 12 or older who used marijuana in the past month, an estimated 40.3 percent used marijuana on 20 or more days within the past month. This equates to approximately 7.6 million individuals aged 12 or older who used marijuana on a daily or almost daily basis.

Additionally, the 2013 MTF data report the prevalence of daily marijuana use, defined as use on 20 or more days within the past 30 days, in 8th, 10th, and 12th graders is 1.1 percent, 4.0 percent, and 6.5 percent, respectively.

Tolerance is a state of adaptation where exposure to a drug induces changes that result in a diminution of one or more of the drug's effects over time (American Academy of Pain Medicine, American Pain Society and American Society of Addiction Medicine consensus document, 2001). Tolerance can develop to some, but not all, of marijuana's effects. Specifically, tolerance does not seem to develop in response to many of marijuana's psychoactive effects. This lack of tolerance may relate to electrophysiological data demonstrating that chronic delta^9-THC administration does not affect increased neuronal firing in the ventral tegmental area, a region known to play a critical role in drug reinforcement and reward (Wu and French, 2000). In the absence of other abuse indicators, such as rewarding properties, the presence of tolerance or physical dependence does not determine whether a drug has abuse potential.

However, humans can develop tolerance to marijuana's cardiovascular, autonomic, and behavioral effects (Jones et al., 1981). Tolerance to some of marijuana's behavioral effects seems to develop after heavy marijuana use, but not after occasional marijuana use. For instance, following acute administration of marijuana, heavy marijuana users did not exhibit impairments in tracking and attention tasks, as were seen in occasional marijuana users (Ramaekers et al., 2009). Furthermore, a neurophysiological assessment administered through an electroencephalograph (EEG) which measures event-related potentials (ERP) conducted in the same subjects as the previous study, found a corresponding effect in the P100[26] component of ERPs. Specifically, corresponding to performance on tracking and attention tasks, heavy marijuana users showed no changes in P100 amplitudes following acute marijuana administration, although occasional users showed a decrease in P100 amplitudes (Theunissen et al., 2012). A possible mechanism underlying tolerance to marijuana's effects may be the down-regulation of cannabinoid receptors (Hirvonen et al., 2012; Gonzalez et al., 2005; Rodriguez de Fonseca et al., 1994; Oviedo et al., 1993).

Importantly, pharmacological tolerance alone does not indicate a drug's physical dependence liability. In order for physical dependence to exist, evidence of a withdrawal syndrome is needed. Physical dependence is a state of adaptation, manifested by a drug-class specific withdrawal syndrome produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist *(ibid)*. Many medications not associated with abuse or addiction can produce physical dependence and withdrawal symptoms after chronic use.

Discontinuation of heavy, chronic marijuana use has been shown to lead to physical dependence and withdrawal symptoms (American Psychiatric Association DSM–V, 2013; Budney and Hughes, 2006; Haney et al., 1999). In heavy, chronic marijuana users, the most commonly reported withdrawal symptoms are sleep difficulties, decreased appetite or weight loss, irritability, anger, anxiety or nervousness, and restlessness. Some less commonly reported withdrawal symptoms are depressed mood, sweating, shakiness, physical discomfort, and chills (Budney and Hughes, 2006; Haney et al., 1999). The occurrence of marijuana withdrawal symptoms in light or non-daily marijuana users has not been established. The American Psychiatric Association's DSM–V (2013) includes a list of symptoms of ''cannabis withdrawal.'' Most marijuana withdrawal symptoms begin within 24–48 hours of discontinuation, peak within 4–6 days, and last for 1–3 weeks. Marijuana withdrawal syndrome has been reported in adolescents and adults admitted for substance abuse treatment.

Based on clinical descriptions, this syndrome appears to be mild compared to classical alcohol and barbiturate withdrawal syndromes, which can include more serious symptoms such as agitation, paranoia, and seizures. Multiple studies comparing marijuana and tobacco withdrawal symptoms in humans demonstrate that the magnitude and time course of the two withdrawal syndromes are similar (Budney et al., 2008; Vandrey et al., 2005, 2008).

8. Whether the Substance is an Immediate Precursor of a Substance Already Controlled Under This Article

Under the eight factor analysis, the Secretary must consider whether marijuana is an immediate precursor of a controlled substance. Marijuana is not an immediate precursor of another controlled substance.

Recommendation

After consideration of the eight factors discussed above, FDA recommends that marijuana remain in Schedule I of the CSA. NIDA concurs with this scheduling recommendation.Marijuana meets the three criteria for placing a substance in Schedule I of the CSA under 21 U.S.C. 812(b)(l):

(1) Marijuana has a high potential for abuse:

A number of factors indicate marijuana's high abuse potential, including the large number of individuals regularly using marijuana, marijuana's widespread use, and the vast amount of marijuana available for illicit use. Approximately 18.9 million individuals in the United States (7.3 percent of the U.S. population) used marijuana monthly in 2012. Additionally, approximately 4.3 million individuals met diagnostic criteria for marijuana dependence or abuse in the year prior to the 2012 NSDUH survey. A 2013 survey indicates that by 12th grade, 36.4 percent of students report using marijuana within the past year, and 22.7 percent report using marijuana monthly. In 2011, 455,668 ED visits were marijuana-related, representing 36.4 percent of all illicit drug-related episodes. Primary marijuana use accounted for 18.1 percent of admissions to drug treatment programs in 2011. Additionally, marijuana has dose-dependent reinforcing effects, as demonstrated by data showing that humans prefer relatively higher doses to lower doses. Furthermore, marijuana use can result in psychological dependence.

(2) Marijuana has no currently accepted medical use in treatment in the United States:

FDA has not approved a marketing application for a marijuana drug product for any indication. The opportunity for scientists to conduct clinical research with marijuana exists, and there are active INDs for marijuana; however, marijuana does not have a currently accepted medical use for treatment in the United States, nor does marijuana have an accepted medical use with severe restrictions.

A drug has a ''currently accepted medical use'' if all of the following five elements have been satisfied:

a. The drug's chemistry is known and reproducible;

b. there are adequate safety studies;

c. there are adequate and well-controlled studies proving efficacy;

d. the drug is accepted by qualified experts; and

e. the scientific evidence is widely available.

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[26] The P100 component of ERPs is thought to relate to the visual processing of stimuli and can be modulated by attention.

[57 FR 10499, March 26, 1992]

Marijuana does not meet any of the elements for having a "currently accepted medical use." First, FDA broadly evaluated marijuana, and did not focus its evaluation on particular strains of marijuana or components or derivatives of marijuana. Since different strains may have different chemical constituents, marijuana, as identified in this petition, does not have a known and reproducible chemistry, which would be needed to provide standardized doses. Second, there are not adequate safety studies on marijuana in the medical literature in relation to a specific, recognized disorder. Third, there are no published adequate and well controlled studies proving efficacy of marijuana. Fourth, there is no evidence that qualified experts accept marijuana for use in treating a specific, recognized disorder. Lastly, the scientific evidence regarding marijuana's chemistry in terms of a specific *Cannabis* strain that could produce standardized and reproducible doses is not currently available, so the scientific evidence on marijuana is not widely available.

Alternately, a Schedule II drug can be considered to have a "currently accepted medical use with severe restrictions" (21 U.S.C. 812(b)(2)(B)). Yet as stated above, the lack of accepted medical use for a specific, recognized disorder precludes the use of marijuana even under conditions where its use is severely restricted.

In conclusion, to date, research on marijuana's medical use has not developed to the point where marijuana is considered to have a "currently accepted medical use" or a "currently accepted medical use with severe restrictions."

(3) There is a lack of accepted safety for use of marijuana under medical supervision:

There are currently no FDA-approved marijuana drug products. Marijuana does not have a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions. Thus, FDA has not determined that marijuana is safe for use under medical supervision.

In addition, FDA cannot conclude that marijuana has an acceptable level of safety relative to its effectiveness in treating a specific, recognized disorder without evidence that the substance is contamination free, and assurance of a consistent and predictable dose. Investigations into the medical use of marijuana should include information and data regarding the chemistry, manufacturing, and specifications of marijuana. Additionally, a procedure for delivering a consistent dose of marijuana should also be developed. Therefore, FDA concludes marijuana does not currently have an accepted level of safety for use under medical supervision.

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The Medical Application of Marijuana: A Review of Published Clinical Studies

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Executive Summary

Marijuana is a Schedule I substance under the Controlled Substances Act (CSA). Schedule I indicates a high potential for abuse, no currently accepted medical use in the United States, and a lack of accepted safety for use under medical supervision. To date, marijuana has not been subject to an approved new drug application (NDA) that demonstrates its safety and efficacy for a specific indication under the Food Drug and Cosmetic Act (FDCA).

Nevertheless, as of October 2014, twenty-three states and the District of

Columbia have passed state-level medical marijuana laws that allow for marijuana use within that state; similar bills are pending in other states.

The present review was undertaken by the Food and Drug Administration (FDA) to analyze the clinical studies published in the medical literature investigating the use of marijuana in any therapeutic areas. First, we discuss the context for this scientific review. Next, we describe the methods used in this review to identify adequate and well-controlled studies evaluating the safety and efficacy of marijuana for particular therapeutic uses.

The FDA conducted a systematic search for published studies in the medical literature that meet the described criteria for study design and outcome measures prior to February 2013. While not part of our systematic review, we have continued to routinely follow the literature beyond that date for subsequent studies. Studies were considered to be relevant to this review if the investigators administered marijuana to patients with a diagnosed medical condition in a well-controlled, double-blind, placebo-controlled clinical trial. Of the eleven studies that met the criteria for review, five different therapeutic areas were investigated:

- Five studies examined chronic neuropathic pain
- Two studies examined appetite stimulation in human immunodeficiency virus (HIV) patients
- Two studies examined glaucoma
- One study examined spasticity and pain in multiple sclerosis (MS)
- One study examined asthma.

For each of these eleven clinical studies, information is provided regarding the subjects studied, the drug conditions tested (including dose and method of administration), other drugs used by subjects during the study, the physiological and subjective measures collected, the outcome of these measures comparing treatment with marijuana to placebo, and the reported and observed adverse events. The conclusions drawn by the investigators are then described, along with potential limitations of these conclusions based on the study design. A brief summary of each study's findings and limitations is provided at the end of the section.

The eleven clinical studies that met the criteria and were evaluated in this review showed positive signals that marijuana may produce a desirable therapeutic outcome, under the specific experimental conditions tested. Notably, it is beyond the scope of this review to determine whether these data demonstrate that marijuana has a currently accepted medical use in the United States. However, this review concludes that these eleven clinical studies serve as proof-of-concept studies, based on the limitations of their study designs, as described in the study summaries. Proof-of-concept studies provide preliminary evidence on a proposed hypothesis regarding a drug's effect. For drugs under development, the effect often relates to a short-term clinical outcome being investigated. Proof-of-concept studies serve as the link between preclinical studies and dose ranging clinical studies. Therefore, proof-of-concept studies are not sufficient to demonstrate efficacy of a drug because they provide only preliminary information about the effects of a drug. However, the studies reviewed produced positive results, suggesting marijuana should be further evaluated as an adjunct treatment for neuropathic pain, appetite stimulation in HIV patients, and spasticity in MS patients.

The main limitations identified in the eleven studies testing the medical applications of marijuana are listed below:

- The small numbers of subjects enrolled in the studies, which limits the statistical analyses of safety and efficacy.
- The evaluation of marijuana only after acute administration in the studies, which limits the ability to determine efficacy following chronic administration.
- The administration of marijuana typically through smoking, which exposes ill patients to combusted material and introduces problems with determining the doses delivered.
- The potential for subjects to identify whether they received marijuana or placebo, which breaks the blind of the studies.
- The small number of cannabinoid naïve subjects, which limits the ability to determine safety and tolerability in these subjects.
- The low number of female subjects, which makes it difficult to generalize the study findings to subjects of both genders.

Thus, this review discusses the following methodological changes that may be made in order to resolve these limitations and improve the design of future studies which examine the safety and efficacy of marijuana for specific therapeutic indications:

- Determine the appropriate number of subjects studied based on recommendations in various FDA *Guidances for Industry* regarding the conduct of clinical trials for specific medical indications.
- Administer consistent and reproducible doses of marijuana based on recommendations in the FDA *Guidance for Industry: Botanical Drug Products (2004).*[27]
- Evaluate the effects of marijuana under therapeutic conditions following both acute and chronic administration.
- Consider alternatives to smoked marijuana (*e.g.,* vaporization).
- Address and improve whenever possible the difficulty in blinding of marijuana and placebo treatments in clinical studies.
- Evaluate the effect of prior experience with marijuana with regard to the safety and tolerability of marijuana.
- Strive for gender balance in the subjects used in studies.

In conclusion, the eleven clinical studies conducted to date do not meet the criteria required by the FDA to determine if marijuana is safe and effective in specific therapeutic areas. However, the studies can serve as proof-of-concept studies and support further research into the use of marijuana in these therapeutic indications. Additionally, the clinical outcome data and adverse event profiles reported in these published studies can beneficially inform how future research in this area is conducted. Finally, application of the recommendations listed above by investigators when designing future studies could greatly improve the available clinical data that can be used to determine if marijuana has validated and reliable medical applications.

1. Introduction

In response to citizen petitions submitted to the Drug Enforcement Administration (DEA) requesting DEA to reschedule marijuana, the DEA Administrator requested that the U.S. Department of Health and Human Services (HHS) provide a scientific and medical evaluation of the available information and a scheduling recommendation for marijuana, in accordance with 21 U.S.C. 811(b). The Secretary of HHS is required to consider in a scientific and medical evaluation eight factors determinative of control under the Controlled Substance Act (CSA). Administrative responsibilities for evaluating a substance for control under the CSA are performed by the Food and Drug Administration (FDA), with the concurrence of the National Institute on Drug Abuse (NIDA). Part of this evaluation includes an assessment of whether marijuana has a currently accepted medical use in the United States. This assessment necessitated a review of the available data from published clinical studies to determine whether there is adequate scientific evidence of marijuana's effectiveness.

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[27] This Guidance is available on the internet at *http://www.fda.gov/Drugs/default.htm* under Guidance (Drugs).

Under Section 202 of the CSA, marijuana is currently controlled as a Schedule I substance (21 U.S.C. 812). Schedule I includes those substances that have a high potential for abuse, have no currently accepted medical use in treatment in the United States, and lack accepted safety for use under medical supervision (21 U.S.C. 812(b)(1)(A)–(C)).

A drug product which has been approved by FDA for marketing in the United States is considered to have a "currently accepted medical use." Marijuana is not an FDA-approved drug product, as a New Drug Application (NDA) or Biologics License application (BLA) for marijuana has not been approved by FDA. However, FDA approval of an NDA is not the only means through which a drug can have a currently accepted medical use in the United States.

In general, a drug may have a "currently accepted medical use" in the United States if the drug meets a five-part test. Established case law (*Alliance for Cannabis Therapeutics* v. *DEA,* 15 F.3d 1131, 1135 (D.C. Cir. 1994)) upheld the Administrator of DEA's application of the five-part test to determine whether a drug has a "currently accepted medical use." The following describes the five elements that characterize "currently accepted medical use" for a drug:[28]

i. The drug's chemistry must be known and reproducible

"The substance's chemistry must be scientifically established to permit it to be reproduced into dosages which can be standardized. The listing of the substance in a current edition of one of the official compendia, as defined by section 201(j) of the Food, Drug and Cosmetic Act, 21 U.S.C. 321(j), is sufficient to meet this requirement."

ii. there must be adequate safety studies

"There must be adequate pharmacological and toxicological studies, done by all methods reasonably applicable, on the basis of which it could fairly and responsibly be concluded, by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, that the substance is safe for treating a specific, recognized disorder."

iii. there must be adequate and well-controlled studies proving efficacy

"There must be adequate, well-controlled, well-designed, well-conducted, and well-documented studies, including clinical investigations, by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, on the basis of which it could be fairly and responsibly concluded by such experts that the substance will have the intended effect in treating a specific, recognized disorder."

iv. the drug must be accepted by qualified experts

"The drug has a New Drug Application (NDA) approved by the Food and Drug Administration, pursuant to the Food, Drug and Cosmetic Act, 21 U.S.C. 355. Or, a consensus of the national community of experts, qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, accepts the safety and effectiveness of the substance for use in treating a specific, recognized disorder. A material conflict of opinion among experts precludes a finding of consensus." and

v. the scientific evidence must be widely available.

"In the absence of NDA approval, information concerning the chemistry, pharmacology, toxicology, and effectiveness of the substance must be reported, published, or otherwise widely available, in sufficient detail to permit experts, qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, to fairly and responsibly conclude the substance is safe and effective for use in treating a specific, recognized disorder."

One way to pass the five-part test for having "currently accepted medical use" is through submission of an NDA or BLA which is approved by FDA. However, FDA approval of an NDA or BLA is not required for a drug to pass the five-part test.

This review focuses on FDA's analysis of one element of the five-part test for determining whether a drug has "currently accepted medical use". Specifically, the present review assesses the 3rd criterion that addresses whether marijuana has "adequate and well-controlled studies proving efficacy". Thus, this review evaluates published clinical studies that have been conducted using marijuana in subjects who have a variety of medical conditions by assessing the adequacy of the summarized study designs and the study data. The methodology for selecting the studies that were evaluated is delineated below.

FDA's evaluation and conclusions regarding the remaining four criteria for whether marijuana has a "currently accepted medical use," as well as the eight factors pertaining to the scheduling of marijuana, are outside the scope of this review. A detailed discussion of these factors is contained in FDA's scientific and medical evaluation of marijuana.

2. Methods

The methods for selecting the studies to include in this review involved the following steps, which are described in detail in the subsections below:

1. Define the objective of the review.
2. Define "marijuana" in order to facilitate the medical literature search for studies that administered the substance,
3. Define "adequate and well-controlled studies" in order to facilitate the search for relevant data and literature,
4. Search medical literature databases and identify relevant adequate and well-controlled studies, and
5. Review and analyze the adequate and well-controlled clinical studies to determine if they demonstrate efficacy of marijuana for any therapeutic indication.

2.1 Define the Objective of the Review

The objective of this review is to assess the study designs and resulting data from clinical studies published in the medical literature that were conducted with marijuana (as defined below) as a treatment for any therapeutic indication, in order to determine if they meet the criteria of "adequate and well-controlled studies proving efficacy".

2.2 Define "Marijuana"

In this review, the term "marijuana" refers to the flowering tops or leaves of the *Cannabis* plant. There were no restrictions on the route of administration used for marijuana in the studies.

Studies which administered individual cannabinoids (whether experimental substances or marketed drug products) or marijuana extracts were excluded from this review. Additionally, studies of administered neutral plant material or placebo marijuana (marijuana with all cannabinoids extracted) that had subsequently been supplemented by the addition of specific amounts of THC or other cannabinoids were also excluded (Chang et al., 1979).

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[28] 57 FR 10499, 10504–06 (March 26, 1992).

2.3 Define "Adequate and Well-Controlled Clinical Studies"

The criteria for an "adequate and well-controlled study" for purposes of determining the safety and efficacy of a human drug is defined under the Code of Federal Regulations (CFR) in 21 CFR 314.126. The elements of an adequate and well-controlled study as described in 21 CFR 314.126 can be summarized as follows:

1. The main objective must be to assess a therapeutically relevant outcome.
2. The study must be placebo-controlled.
3. The subjects must qualify as having the medical condition being studied.
4. The study design permits a valid comparison with an appropriate control condition.
5. The assignment of subjects to treatment and control groups must be randomized.
6. There is minimization of bias through the use of a double-blind study design.
7. The study report contains a full protocol and primary data.
8. Analysis of the study data is appropriately conducted.

As noted above, the current review examines only those data available in the public domain and thus relies on clinical studies published in the medical literature. Published studies by their nature are summaries that do not include the level of detail required by studies submitted to FDA in an NDA.

While the majority of the elements defining an adequate and well-controlled study can be satisfied through a published paper (elements #1–6), there are two elements that cannot be met by a study published in the medical literature: element #7 (availability of a study report with full protocol and primary data) and element #8 (a determination of whether the data analysis was appropriate). Thus, for purposes of this review, only elements #1–6 will be used to qualify a study as being adequate and well-controlled.

2.4 Search Medical Literature Databases and Identify Relevant Studies

We identified randomized, double-blind, placebo-controlled clinical studies conducted with marijuana to assess marijuana's efficacy in any therapeutic indication. Two primary medical literature databases were searched for all studies posted to the databases prior to February 2013: [29]

- *PubMed:* PubMed is a database of published medical and scientific studies that is maintained by the U.S. National Library of Medicine (NLM) at NIH as a part of the Entrez system of information retrieval. PubMed comprises more than 24 million citations for biomedical literature from MEDLINE, life science journals, and online books (*http://www.ncbi.nlm.nih.gov/pubmed*).
- *ClinicalTrials.gov:* ClinicalTrials.gov is a database of publicly and privately supported clinical studies that is maintained by the NLM. Information about the clinical studies is provided by the Sponsor or Principal Investigator of the study. Information about the studies is submitted to the Web site ("registered") when the studies begin, and is updated throughout the study. In some cases, results of the study or resulting publication citations are submitted to the Web site after the study ends (*https://clinicaltrials.gov/ct2/about-site/background*).

ClinicalTrials.gov was searched for all studies administering marijuana. The results of this search were used to confirm that no completed studies with published data were missed in the literature search. During the literature search, references found in relevant studies and systematic reviews were evaluated for additional relevant citations. All languages were included in the search. The PubMed search yielded a total of 566 abstracts.[30] Of these abstracts, a full-text review was conducted with 85 papers to assess eligibility. From this evaluation, only eleven of 85 studies met the 6 CFR elements for inclusion as adequate and well-controlled studies.

Figure 1 (below) provides an overview of the process used to identify studies from the PubMed search. The eleven studies reviewed were published between 1974 and 2013. Ten of these studies were conducted in the United States and one study was conducted in Canada. These eleven studies examined the effects of smoked and vaporized marijuana for the indications of chronic neuropathic pain, spasticity related to multiple sclerosis (MS), appetite stimulation in patients with human immunodeficiency virus (HIV), glaucoma, and asthma. All included studies used adult patients as subjects. All studies conducted in the United States were conducted under an IND as Phase 2 investigations.

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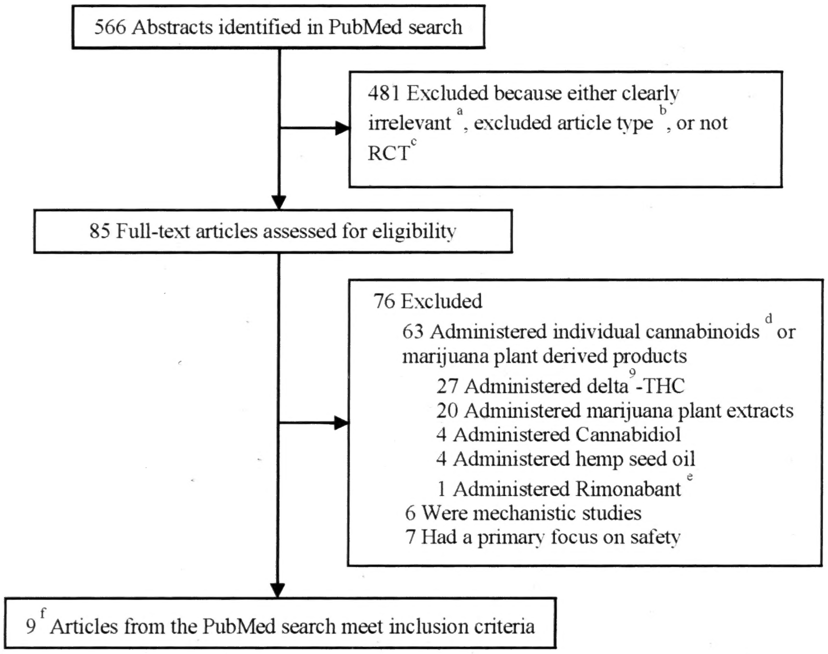
[29] While not a systematic review, we have followed the recent published literature on marijuana use for possible therapeutic purposes and, as of January 2015, we found only one new study that would meet our criteria (Naftali et al., 2013). This study examined the effects of smoked marijuana on Crohn's disease.

[30] The following search strategy was used, "(cannabis OR marijuana) AND (therapeutic use OR therapy) AND (RCT OR randomized controlled trial OR "systematic review" OR clinical trial OR clinical trials) NOT ("marijuana abuse"[Mesh] OR addictive behavior OR substance related disorders)".

Figure 1: Identification of Studies from PubMed Search


566 Abstracts identified in PubMed search
481 Excluded because either clearly irrelevant [a], excluded article type [b], or not RCT [c]
85 Full-text articles assessed for eligibility
76 Excluded
63 Administered individual cannabinoids [d] or marijuana plant derived products
27 Administered delta^9-THC
20 Administered marijuana plant extracts
4 Administered Cannabidiol
4 Administered hemp seed oil
1 Administered Rimonabant [e]
6 Were mechanistic studies
7 Had a primary focus on safety
9 [f] Articles from the PubMed search meet inclusion criteria

[a]Articles were deemed irrelevant if they examined safety or adverse event related outcomes, including psychoactive effects or other adverse events. [b]Excluded article types included comments, reviews, meta-analyses, and news articles. [c]Randomized Controlled Trials. [d]Cannabinoids administered included synthetic cannabinoids. [e]Rimonabant is a cannabinoid receptor antagonist. [f]An additional 2 studies meeting the inclusion criteria were found through the reference search.

Two qualifying studies, which assessed marijuana for glaucoma, were previously reviewed in the 1999 Institute of Medicine (IOM) report entitled "Marijuana and Medicine: Assessing the Science Base".[31] We did our own analysis of these two studies and concurred with the conclusions in the IOM report. Thus, a detailed discussion of the two glaucoma studies is not included in the present review. The present review only discusses 9 of the identified 11 studies. For a summary of the study design for all eleven qualifying studies, see Tables 1–5 (located in the Appendix).

Based on the selection criteria for relevant studies described in Section 2.3 (Define Adequate and Well-Controlled Clinical Studies), a number of clinical studies that investigated marijuana, as defined in this review, were excluded from this review. Studies that examined the effects of marijuana in healthy subjects were excluded because they did not test a patient population with a medical condition (Flom et al., 1975; Foltin et al., 1986; Foltin et al., 1988; Hill et al., 1974; Milstein et al., 1974; Milstein et al., 1975; Soderpalm et al., 2001; Wallace et al., 2007; Greenwald and Stitzer, 2000). A 1975 study by Tashkin et al. was excluded because it had a single-blind, rather than double-blind, study design. Two other studies were excluded because the primary outcome measure assessed safety rather than a therapeutic outcome (Greenberg et al., 1994; Abrams et al., 2003).

2.5 Review and Analyze Qualifying Clinical Studies

Qualified clinical studies that evaluated marijuana for therapeutic purposes were examined in terms of adequacy of study design including method of drug administration, study size, and subject inclusion and exclusion criteria. Additionally, the measures and methods of analysis used in the studies to assess the treatment effect were examined.

3. Results and Discussion

The eleven qualifying studies in this review assessed a variety of therapeutic indications. In order to better facilitate analysis and discussion of the studies, the following sections group the studies by therapeutic area. Within each section, each individual study is summarized in terms of its design, outcome data and important limitations. This information is also provided in the Appendix in tabular form for each study.

3.1 Neuropathic Pain

Five randomized, double-blind, placebo-controlled Phase 2 clinical studies have been conducted to examine the effects of inhaled marijuana smoke on neuropathic pain associated with HIV-sensory neuropathy (Abrams et al., 2007; Ellis et al., 2009) and chronic neuropathic pain from multiple causes

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[31] In January 1997, the White House Office of National Drug Control Policy (ONDCP) requested that the IOM conduct a review of the scientific evidence to assess the potential health benefits and risks of marijuana and its constituent cannabinoids. Information for this study was gathered through scientific workshops, site visits to cannabis buyers' clubs and HIV/Acquired Immunodeficiency Syndrome (AIDS) clinics, analysis of the relevant scientific literature, and extensive consultation with biomedical and social scientists. The report was finalized and published in 1999.

(Wilsey et al., 2008; Ware et al., 2010; Wilsey et al., 2013). Table 1 of the Appendix summarizes these studies.

3.1.1 Neuropathic Pain Associated With HIV-Sensory Neuropathy

Two studies examined the effect of marijuana to reduce the pain induced by HIV-sensory neuropathy.

Abrams et al. (2007) conducted the first study entitled, "Cannabis in painful HIV-associated sensory neuropathy: A randomized placebo-controlled trial". The subjects were 50 adult patients with uncontrolled HIV-associated sensory neuropathy, who had at least 6 experiences with smoking marijuana. The subjects were split into two parallel groups of 25 subjects each. More than 68% of subjects were current marijuana users, but all individuals were required to discontinue using marijuana prior to the study. Most subjects were taking medication for pain during the study, with the most common medications being opioids and gabapentin. Upon entry into the study, subjects had an average daily pain score of at least 30 on a 0–100 visual analog scale (VAS).

Subjects were randomized to receive either smoked marijuana (3.56% THC[32]) or smoked placebo cigarettes three times per day for 5 days, using a standardized cued smoking procedure: (1) 5 second inhale, (2) 10 second holding smoke in the lungs, (3) 40 second exhale and breathing normally between puffs. The authors did not specify how many puffs the subjects smoked at each smoking session, but they stated that one cigarette was smoked per smoking session.

Primary outcome measures included daily VAS ratings of chronic pain and the percentage of subjects who reported a result of more than 30% reduction in pain intensity. The ability of smoked marijuana to induce acute analgesia was assessed using both thermal heat model and capsaicin sensitization model, while anti-hyperalgesia was assessed with brush and von Frey hair stimuli. The immediate analgesic effects of smoked marijuana was assessed using a 0–100 point VAS at 40-minute intervals three times before and three times after the first and last smoking sessions, which was done to correspond to the time of peak plasma cannabinoid levels. Notably, not all subjects completed the induced pain portion of the study (n = 11 in marijuana group, 9 in placebo group) because of their inability to tolerate the stimuli. Throughout the study, subjects also completed the Profile of Mood States (POMS) questionnaire, as well as subjective VAS measures of anxiety, sedation, disorientation, paranoia, confusion, dizziness, and nausea.

As a result, the median daily pain was reduced 34% by smoked marijuana compared to 17% by placebo ($p = 0.03$). Fifty-two percent of subjects who smoked marijuana reported a >30% reduction in pain compared to 24% in the placebo group ($p = 0.04$). Although marijuana reduced experimentally-induced hyperalgesia ($p \leq 0.05$) during the first smoking sessions, marijuana did not alter responses to acutely painful stimuli.

There were no serious AEs and no episodes of hypertension, hypotension, or tachycardia requiring medical intervention. No subjects withdrew from the study for drug related reasons. Subjects in the marijuana group reported higher ratings on the subjective measures of anxiety, sedation, disorientation, confusion, and dizziness compared to the placebo group. There was one case of severe dizziness in a marijuana-treated subject. By the end of the study, subjects treated with marijuana and placebo reported a reduction in total mood disturbance as measured by POMS.

The authors conclude that smoked marijuana effectively reduced chronic neuropathic pain from HIV-associated sensory neuropathy with tolerable side effects. However, limitations of this study include: Maintenance of subjects on other analgesic medication while being tested with marijuana and a lack of information about the number of puffs during each inhalation of smoke. These limitations make it difficult to conclude that marijuana has analgesic properties on its own and that the actual AEs experienced during the study in response to marijuana are tolerable. However, the study produced positive results suggesting that marijuana should be studied further as an adjunct treatment for uncontrolled HIV-associated sensory neuropathy.

Ellis et al. (2009) conducted a more recent study entitled "Smoked medicinal cannabis for neuropathic pain in HIV: a randomized, crossover clinical trial". The subjects were 28 HIV-positive adult male patients with intractable neuropathic pain that was refractory to the effects of at least two drugs taken for analgesic purposes. Upon entry into the study, subjects had a mean score of >5 on the Pain Intensity subscale of the Descriptor Differential Scale (DDS). Subjects were allowed to continue taking their current routine of pain medications, which included opioids, non-narcotic analgesics, antidepressants, and anticonvulsants. Previous experience with marijuana was not required for participation in the study, but 27 of 28 subjects (96%) reported previous experience with marijuana. However, of these 27 experienced subjects, 63% (n = 18) reported no marijuana use within the past year.

The study procedures compared the effects of the target dose of marijuana and placebo during two treatment periods lasting 5 days, with 2 weeks washout periods. The marijuana strengths available were 1%, 2%, 4%, 6%, or 8% THC concentration by weight. Subjects smoked marijuana or placebo cigarettes four times per day, approximately 90–120 minutes apart, using a standardized cued smoking procedure: (1) 5 second smoke inhalation, (2) 10 second hold of smoke in lungs, (3) 40 second exhale and normal breathing between puffs. The investigators did not provide a description of the number of puffs taken at any smoking session. All subjects practiced the smoking procedures using placebo marijuana prior to test sessions.

On the first day of each test period, dose titration occurred throughout the four smoking sessions scheduled for that day, with a starting strength of 4% THC concentration. Subjects were allowed to titrate to a personalized "target dose", which was defined as the dose that provided the best pain relief without intolerable adverse effects. This dose titration was accomplished by allowing subjects to either increase the dose incrementally (to 6% or 8% THC) to improve analgesia, or to decrease the dose incrementally (to 1% or 2% THC) if AEs were intolerable. For the next 4 days of each test period, the subjects smoked their target dose during each of the four daily smoking sessions. To maintain the blind, placebo marijuana was represented as containing 1%–8% THC, even though it did not contain any cannabinoids.

The primary outcome measure was the change in pain magnitude on the DDS at the end of each test period compared to baseline, with a clinically significant level of analgesia considered to be a reduction in pain of at least 30%. Additional measures included the POMS, the Sickness Impact Profile (SIP), the Brief Symptom Inventory (BSI) and the UKU Side Effect Rating Scale and a subjective highness/sedation VAS.

During the marijuana treatment week, 19 subjects titrated to the 2%–4% THC dose while the 6%–8% dose was preferred by 8 subjects and 1 subject chose the 1% dose. In contrast, during the placebo treatment week, all 28 subjects titrated to the highest possible dose of "8% THC" that contained no actual cannabinoids, suggesting that placebo treatment provided little analgesic relief.

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[32] The drug dose is reported as percentage of THC present in the marijuana rather than milligrams of THC present in each cigarette because of the difficulty in determining the amount of THC delivered by inhalation (see discussion in the section entitled "3.7.2 Marijuana Dose Standardization").

The degree of pain reduction was significantly greater after administration of marijuana compared to placebo (median change of 3.3 points on DDS, $p = 0.016$). The median change from baseline in VAS pain scores was −17 for marijuana treatment compared to −4 for placebo treatment ($p < 0.001$). A larger proportion of subjects who were treated with marijuana (0.46) reported a >30% reduction in pain, compared to placebo (0.18). Additionally, the authors report improvements in total mood disturbance, physical disability, and quality of life as measured on POMS, SIP, and BSI scales after both placebo and marijuana treatment (data not provided in paper).

In terms of safety, there were no alterations in HIV disease parameters in response to marijuana or placebo. The authors report that marijuana led to a greater degree of UKU responses as well as AEs such as difficulty in concentration, fatigue, sleepiness or sedation, increased duration of sleep, reduced salivation and thirst compared to placebo (data not provided in paper). Two subjects withdrew from the study because of marijuana-related AEs: one subject developed an intractable smoking-related cough during marijuana administration and the sole marijuana-naïve subject in the study experienced an incident of acute cannabis-induced psychosis.[33]

The authors conclude that smoked marijuana effectively reduced chronic neuropathic pain from HIV-associated sensory neuropathy. The limitations of this study include: a lack of information about the number of puffs during each inhalation of smoke; a lack of information about the specific timing of the subjective assessments and collection of AEs relative to initiation of the smoking sessions; and the inclusion of only one marijuana-naïve subject. These limitations make it difficult to conclude that the actual AEs experienced during the study in response to marijuana are tolerable. It is especially concerning that the only marijuana-naïve subject left the study because of serious psychiatric responses to marijuana exposure at analgesic doses. However, the study produced positive results suggesting that marijuana should be studied further as an adjunct treatment for uncontrolled HIV-associated sensory neuropathy.

3.1.2 Central and Peripheral Neuropathic Pain

Three studies examined the effect of marijuana on chronic neuropathic pain.

Wilsey et al. (2008) examined chronic neuropathic pain from multiple causes in the study entitled, "A Randomized, Placebo-Controlled, Crossover Trial of Cannabis Cigarettes in Neuropathic Pain". The subjects were 32 patients with a variety of neuropathic pain conditions, including 22 with complex regional pain syndrome, 6 with spinal cord injury, 4 with multiple sclerosis, 3 with diabetic neuropathy, 2 with ilioinguinal neuralgia, and 1 with lumbosacral plexopathy. All subjects reported a pain intensity of at least 30 on a 0–100 VAS and were allowed to continue taking their regular medications during the study period, which included opioids, antidepressants, anticonvulsants, and NSAIDs. All subjects were required to have experience with marijuana but could not use any cannabinoids for 30 days before study sessions.

The study consisted of three test sessions with an interval of 3–21 days between sessions. Treatment conditions were high-strength marijuana (7% delta-9-THC), low-strength marijuana (3.5% delta-9-THC), and placebo cigarettes, administered through a standardized cued-puff procedure: (1) "light the cigarette" (30 seconds), (2) "get ready" (5 seconds), (3) "inhale" (5 seconds), (4) "hold smoke in lungs" (10 seconds), (5) "exhale," and (6) wait before repeating the puff cycle (40 seconds). Participants took 2 puffs after baseline measurements, 3 puffs an hour later, and 4 puffs an hour after that, for a cumulative dose of 9 puffs per test session.

Hourly assessment periods were scheduled before and after each set of puffs and for 2 additional hours during the recovery period. Plasma cannabinoids were measured at baseline, 5 minutes after the first puff and again at 3 hours after the last puff cycle.

The primary outcome measure was spontaneous pain relief, as measured by a 0–100 point VAS for current pain. Pain unpleasantness was measured on a 0–100 point VAS, and degree of pain relief was measured on a 7-point Patient Global Impression of Change (PGIC) scale. Secondary measures included the Neuropathic Pain Scale (NPS), a 0–100 point VAS for allodynia, and changes in thermal pain threshold. Subjective measures were also evaluated with unipolar 0–100 point VAS for any drug effect, good drug effect, bad drug effect, high, drunk, impaired, stoned, like the drug effect, sedated, confused, nauseated, desire more of the drug, anxious, down, hungry, and bipolar 0–100 point VAS for sad/happy, anxious/relaxed, jittery/calm, bad/good, paranoid/self-assured, fearful/unafraid. Neurocognitive assessments measured attention and concentration, learning and memory, and fine motor speed.

Marijuana produced a reduction in pain compared to placebo, as measured by the pain VAS, the PGIC and on pain descriptors in the NPS, including sharp ($P < .001$), burning ($P < .001$), aching ($P < .001$), sensitive ($P = .03$), superficial ($P < .01$) and deep pain ($P < .001$). Notably, there were no additional benefits from the 7% THC strength of marijuana compared to the 3.5% THC strength, seemingly because of cumulative drug effects over time. There were no changes in allodynia or thermal pain responsivity following administration of either dose of marijuana.

Marijuana at both strengths produced increases on measures of any drug effect, good drug effect, high, stoned, impairment, sedation, confusion, and hunger. The 7% THC marijuana increased anxiety scores and bad drug effect (later in session) compared to placebo. Neither strength of marijuana affected the measures of mood. On neurocognitive measures, both the 3.5% THC and 7% THC marijuana produced impairment in learning and memory, while only the 7% THC marijuana impaired attention and psychomotor speed, compared to placebo. There were no adverse cardiovascular side effects and no subjects dropped out because of an adverse event related to marijuana.

The authors conclude that marijuana may be effective at ameliorating neuropathic pain at doses that induce mild cognitive effects, but that smoking is not an optimum route of administration. The limitations of this study include: Inclusion of subjects with many forms of neuropathic pain and maintenance of subjects on other analgesic medication while being tested with marijuana. These limitations make it difficult to conclude that marijuana has analgesic properties on its own and that the actual AEs experienced during the study in response to marijuana are tolerable. The authors compared pain score results by the type of pain condition, with no significant differences found; however, the sample size of this study was small thus a type II error may have been present. Thus, it is difficult to determine if any particular subset of neuropathic pain conditions would benefit specifically from marijuana administration. However, the study produced positive results suggesting that marijuana should be studied further as an adjunct treatment for uncontrolled neuropathic pain.

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[33] At the time of the study, the following criteria from the Diagnostic and Statistical Manual of Mental Disorders (DSM–IV–TR, 2000) were used to diagnose substance-induced psychotic disorders: Prominent hallucinations or delusions; Hallucinations and/or delusions that develop during, or within one month of, intoxication or withdrawal; The disturbance is not better accounted for by a psychotic disorder that is not substance induced. The disturbance does not occur exclusively during the course of a delirium.

The second study, conducted by Ware et al. (2010) in Canada is entitled, "Smoked cannabis for chronic neuropathic pain: a randomized controlled trial". The subjects were 21 adult patients with neuropathic pain caused by trauma or surgery compounded with allodynia or hyperalgesia, and a pain intensity score greater than 4 on a 10 point VAS. All subjects maintained their current analgesic medication and they were allowed to use acetaminophen for breakthrough pain. Eighteen subjects had previous experience with marijuana but none of them had used marijuana within a year before the study.

The study design used a four-period crossover design, testing marijuana (2.5%, 6.0% and 9.4% THC) and placebo marijuana. The 2.5% and 6.0% doses of marijuana were included to increase successful blinding. Each period was 14 days in duration, beginning with 5 days on the study drug followed by a 9-day washout period. Doses were delivered as 25 mg of marijuana that was smoked in a single inhalation using a titanium pipe. The first dose of each period was self-administered using a standardized puff procedure: (1) Inhale for 5 seconds, (2) hold the smoke in their lungs for 10 seconds, and (3) exhale. Subsequent doses were self-administered in the same manner for a total of three times daily at home on an outpatient basis for the first five days of each period.

The primary measure was an 11-point pain intensity scale, averaged over the 5 day treatment period, which was administered once daily for present, worst, least and average pain intensity during the previous 24 hours. Secondary measures included an acute pain 0–100 point VAS, pain quality assessed with the McGill Pain Questionnaire, sleep assessed with the Leeds Sleep Evaluation Questionnaire, mood assessed with the POMS, quality of life assessed using the EQ–5D health outcome instrument. Subjective measures included 0–100 point VAS scales for high, relaxed, stressed and happy.

Over the first three hours after smoking marijuana, ratings of pain, high, relaxation, stress, happiness and heart rate were recorded. During the five days of each study period, participants were contacted daily to administer questionnaires on pain intensity, sleep, medication and AEs. Subjects returned on the fifth day to complete questionnaires on pain quality, mood, quality of life and assessments of potency. At the end of the study, participants completed final adverse event reports and potency assessments.

The average daily pain intensity was significantly lower on 9.4% THC marijuana (5.4) than on placebo marijuana (6.1) ($p = 0.023$). The 9.4% THC strength also produced more drowsiness, better sleep, with less anxiety and depression, compared to placebo (all $p < 0.05$). However, there were no significant differences on POMS scores or on VAS scores for high, happy, relaxed or stressed between THC doses.

The most frequent drug-related adverse events reported in the group receiving 9.4% THC marijuana were headache, dry eyes, burning sensation, dizziness, numbness and cough. Reports of high and euphoria occurred on only three occasions, once in each dose of THC. There were no significant changes in vital signs, heart-rate variability, or renal function. One subject withdrew from the study due to increased pain during administration of 6% THC marijuana.

The authors conclude that smoked marijuana reduces neuropathic pain, improves mood and aids in sleep, but that smoking marijuana is not a preferable route of administration. The limitations of this study include: The lack of information on timing of assessments during the outpatient portion of the study and maintenance of subjects on other analgesic medication while being tested with marijuana. These limitations make it difficult to conclude that marijuana has analgesic properties on its own and that the actual AEs experienced during the study in response to marijuana are tolerable. However, the study produced positive results suggesting that marijuana should be studied further as an adjunct treatment for uncontrolled neuropathic pain.

Wilsey et al. (2013) conducted the most recent study entitled, "Low-Dose Vaporized Cannabis Significantly Improves Neuropathic Pain". This study is the only one in this review that utilized vaporization as a method of marijuana administration. The subjects were 36 patients with a neuropathic pain disorder (CRPS, thalamic pain, spinal cord injury, peripheral neuropathy, radiculopathy, or nerve injury) who were maintained on their current medications (opioids, anticonvulsants, antidepressants, and NSAIDs). Although subjects were required to have a history of marijuana use, they refrained from use of cannabinoids for 30 days before study sessions.

Subjects participated in three sessions in which they received 1.29% or 3.53% THC marijuana or placebo marijuana. The marijuana was vaporized using the Volcano vaporizer and a standardized cued-puff procedure: (1) "hold the vaporizer bag with one hand and put the vaporizer mouthpiece in their mouth" (30 seconds), (2) "get ready" (5 seconds), (3) "inhale" (5 seconds), (4) "hold vapor in lungs" (10 seconds), (5) "exhale and wait" before repeating puff cycle (40 seconds). Subjects inhaled 4 puffs at 60 minutes. At 180 minutes, the vaporizer was refilled with marijuana vapor and subjects were allowed to inhale 4 to 8 puffs using the cued procedure. Thus, cumulative dosing allowed for a range of 8 to12 puffs in total for each session, depending on the subjects desired response and tolerance. The washout time between each session ranged from 3–14 days.

The primary outcome variable was spontaneous pain relief, as assessed using a 0–100 point VAS for current pain. Secondary measures included the Patient Global Impression of Change (PGIC), the Neuropathic Pain Scale (NPS), a 0–100 point VAS for allodynia. Acute pain threshold was measured with a thermal pain model. Subjective measures included 0–100 point unipolar VAS for any drug effect, good drug effect, bad drug effect, high, drunk, impaired, stoned, drug liking, sedated, confused, nauseated, desire more drug, anxious, down and hungry. Bipolar 0–100 point VAS included sad/happy, anxious/relaxed, jittery/calm, bad/good, paranoid/self-assured, and fearful/unafraid.

Neurocognitive assessments assessed attention and concentration, learning and memory, and fine motor speed.

A 30% reduction in pain was achieved in 61% of subjects who received the 3.53% THC marijuana, in 57% of subjects who received the 1.29% THC marijuana and in 26% of subjects who received the placebo marijuana ($p = 0.002$ for placebo vs. 3.53% THC, $p = 0.007$ for placebo vs 1.29% THC; $p \leq 0.05$ 1.29% THC vs. 3.53% THC). Both strengths of marijuana significantly decreased pain intensity, unpleasantness, sharpness, and deepness on the NPS, as well as pain ratings on the PGIC, compared to placebo. These effects on pain were maximal with cumulative dosing over the course of the study session, with maximal effects at 180 minutes. There were no effects of marijuana compared to placebo on measures of allodynia or thermal pain. Subjects correctly identified the study treatment 63% of the time for placebo, 61% of the time for 1.29% THC, and 89% of the time for 3.53% THC.

On subjective measures, marijuana produced dose-dependent increases compared to placebo on ratings for: any drug effect, good drug effect, drug liking, high, stoned, sedated, confused, and hungry. Both strengths of marijuana produced similar increases in drunk or impaired compared to placebo. In contrast, desire for drug was rated as higher for the 1.29% THC marijuana compared to the 3.53% THC marijuana. There were no changes compared to placebo for bad effect, nauseous, anxiety, feeling down or any of the bipolar mood assessments. There was dose-dependent impairment on learning and memory from marijuana compared to placebo, but similar effects between the two strengths of marijuana on attention.

The authors conclude that vaporization of relatively low doses of marijuana can produce improvements in analgesia in neuropathic pain patients, especially when patients are allowed to titrate their exposure. However, this individualization of doses may account for the general lack of difference between the two strengths of marijuana. No data were presented regarding the total amount of THC consumed by each subject, so it is difficult to determine a proper dose-response evaluation. Additional limitations of this study are the inclusion of subjects with many forms of neuropathic pain and maintenance of subjects on other analgesic medication while being tested with marijuana. These limitations make it difficult to conclude that marijuana has analgesic properties on its own. It is also difficult to determine if any particular subset of neuropathic pain conditions would benefit specifically from marijuana administration. However, the study produced positive results suggesting that marijuana should be studied further as an adjunct treatment for uncontrolled neuropathic pain.

3.2 Appetite Stimulation in HIV

Two randomized, double-blind, placebo-controlled Phase 2 studies examined the effects of smoked marijuana on appetite in HIV-positive subjects (Haney et al., 2005; Haney et al., 2007). Table 2 of the Appendix summarizes both studies.

The first study, conducted by Haney et al. (2005) is entitled, ''Dronabinol and marijuana in HIV+ marijuana smokers: Acute effects on caloric intake and mood''. The subjects were 30 HIV-positive patients who were maintained on two antiretroviral medications and either had clinically significant decreases in lean muscle mass[34] (low-BIA group, n = 15) or normal lean muscle mass (normal-BIA group, n = 15). All subjects had a history of smoking marijuana at least twice weekly for 4 weeks prior to entry into the study. On average, individuals had smoked 3 marijuana cigarettes per day, 5–6 times per week for 10–12 years.

Subjects participated in 8 sessions that tested the acute effects of 0, 10, 20, and 30 mg dronabinol oral capsules and marijuana cigarettes with 0%, 1.8%, 2.8%, and 3.9% THC concentration by weight, using a double-dummy design (with only one active drug per session). The doses of dronabinol are higher than those doses typically prescribed for appetite stimulation in order to help preserve the blinding. There was a one-day washout period between test sessions.

Marijuana was administered using a standardized cued procedure: (1) ''light the cigarette'' (30 seconds), (2) ''prepare'' (5 seconds), (3) ''inhale'' (5 seconds), (4) ''hold smoke in lungs'' (10 seconds), and (5) ''exhale.'' Each subject smoked three puffs in this manner, with a 40-second interval between each puff.

Caloric intake was used as a surrogate measure for weight gain. Subjects received a box containing a variety of food and beverage items and were told to record consumption of these items following that day's administration of the test drug. Subjective measures included 0–100 point VAS for feel drug effect, good effect, bad effect, take drug again, drug liking, hungry, full, nauseated, thirsty, desire to eat. Neurocognitive measures and vital signs were monitored.

The low BIA group consumed significantly more calories in the 1.8% and 3.9% THC marijuana conditions ($p<0.01$) and the 10, 20, and 30 mg dronabinol conditions ($p<0.01$) compared with the placebo condition. In contrast, in the normal BIA group, neither marijuana nor dronabinol significantly affected caloric intake. This lack of effect may be accountable, however, by the fact that this group consumed approximately 200 calories more than the low BIA group under baseline conditions.

Ratings of high and good drug effect were increased by all drug treatments in both the low-BIA and normal-BIA groups, except in response to the 10 mg dose of dronabinol. The 3.9% THC marijuana increased ratings of good drug effect, drug liking and desire to smoke again compared with placebo. Ratings of sedation were increased in both groups by 10 and 30 mg dronabinol, and in the normal BIA group by the 2.8% THC marijuana. Ratings of stimulation were increased in the normal BIA group by 2.8% and 3.9% THC marijuana and by 20 mg dronabinol. Increases in ratings of forgetfulness, withdrawn, dreaming, clumsy, heavy limbs, heart pounding, jittery, and decreases in ratings of energetic, social, and talkative were reported in the normal BIA group with 30 mg dronabinol. There were no significant changes in vital signs or performance on neurocognitive measures in response to marijuana. Notably, the time course of subjective effects peaked quickly and declined thereafter for smoked marijuana, while oral dronabinol responses took longer to peak and persisted longer. Additionally, marijuana but not dronabinol produced dry mouth and thirst.

In general, AEs reported in this study were low in both drug conditions for both subject groups. In the low BIA group, nausea was reported by one subject in both the 10 and 20 mg dronabinol conditions, while an uncomfortable level of intoxication was produced by the 30 mg dose in two subjects. There were no AEs reported in this group following marijuana at any dose. In the normal BIA group, the 30 mg dose of dronabinol produced an uncomfortable level of intoxication in three subjects and headache in one subject, while the 3.9% marijuana produced diarrhea in one subject.

The authors conclude that smoked marijuana can acutely increase caloric intake in low BIA subjects without significant cognitive impairment. However, it is possible that the low degree of cognitive impairment reported in this study may reflect the development of tolerance to cannabinoids in this patient population, since all individuals had current histories of chronic marijuana use. Additional limitations in this study include not utilizing actual weight gain as a primary measure. However, the study produced positive results suggesting that marijuana should be studied further as a treatment for appetite stimulation in HIV patients.

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[34] Lean muscle mass was assessed using bioelectrical impedance analysis (BIA). The low-BIA group was classified with having <90% BIA, and the normal-BIA group was classified with having >90% BIA.

A second study conducted by Haney et al. (2007) is entitled, "Dronabinol and marijuana in HIV-positive marijuana smokers: Caloric intake, mood, and sleep". The design of this study was nearly identical to the one conducted by this laboratory in 2005 (see above), but there was no stratification of subjects by BIA. The subjects were 10 HIV-positive patients who were maintained on two antiretroviral medications and had a history of smoking marijuana at least twice weekly for 4 weeks prior to entry into the study. On average, individuals had smoked 3 marijuana cigarettes per day, 5 times per week for 19 years.

Subjects participated in 8 sessions that tested the acute effects of 0, 5 and 10 mg dronabinol oral capsules and marijuana cigarettes with 0, 2.0% and 3.9% THC concentration by weight, using a double-dummy design (with 4 sessions involving only one active drug and 4 interspersed placebo sessions). Both drug and placebo sessions lasted for 4 days each, with active drug administration occurring 4 times per day (every 4 hours). Testing occurred in two 16-day inpatient stays. In the intervening outpatient period, subjects were allowed to smoke marijuana prior to re-entry to the study unit for the second inpatient stay.

Marijuana was administered using a standardized cued procedure: (1) "light the cigarette" (30 seconds), (2) "prepare" (5 seconds), (3) "inhale" (5 seconds), (4) "hold smoke in lungs" (10 seconds), and (5) "exhale." Each subject smoked three puffs in this manner, with a 40-second interval between each puff.

Caloric intake was used as a surrogate measure for weight gain, but subjects were also weighed throughout the study (a measure which was not collected in the 2005 study by this group). Subjects received a box containing a variety of food and beverage items and were told to record consumption of these items following that day's administration of the test drug. Subjective measures included 0–100 point VAS for drug effect, good effect, bad effect, take drug again, drug liking, hungry, full, nauseated, thirsty, desire to eat. Neurocognitive measures and vital signs were monitored. Sleep was assessed using both the Nightcap sleep monitoring system and selected VAS measures related to sleep.

Both 5 and 10 mg dronabinol ($p < 0.008$) and 2.0% and 3.9% THC marijuana ($p < 0.01$) dose-dependently increased caloric intake compared with placebo. This increase was generally accomplished through increases in incidents of eating, rather than an increase in the calories consumed in each incident. Subjects also gained similar amounts of weight after the highest dose of each cannabinoid treatment: 1.2 kg (2.6 lbs) after 4 days of 10 mg dronabinol, and 1.1 kg (2.4 lbs) after 4 days of 3.9% THC marijuana. The 3.9% THC marijuana dose also increased the desire to eat and ratings of hunger.

Ratings of good drug effect, high, drug liking, and desire to smoke again were significantly increased by 10 mg dronabinol and 2.0% and 3.9% THC marijuana doses compared to placebo. Both marijuana doses increased ratings of stimulated, friendly, and self-confident. The 10 mg dose of dronabinol increased ratings of concentration impairment, and the 2.0% THC marijuana dose increased ratings of anxious. Dry mouth was induced by 10 mg dronabinol (10 mg) and 2.0% THC marijuana. There were no changes in neurocognitive performance or objective sleep measures from administration of either cannabinoid. However, 3.9% THC marijuana increased subjective ratings of sleep.

The authors conclude that both dronabinol and smoked marijuana increase caloric intake and produce weight gain in HIV-positive patients. However, it is possible that the low degree of cognitive impairment reported in this study may reflect the development of tolerance to cannabinoids in this subject population, since all individuals had current histories of chronic marijuana use. This study produced positive results suggesting that marijuana should be studied further as a treatment for appetite stimulation in HIV patients.

3.3 *Spasticity in Multiple Sclerosis*

Only one randomized, double-blind, placebo-controlled Phase 2 study examined the effects of smoked marijuana on spasticity in MS.

This study was conducted by Corey-Bloom et al. (2012) and is entitled, "Smoked cannabis for spasticity in multiple sclerosis: a randomized, placebo-controlled trial". The subjects were 30 patients with MS-associated spasticity and had moderate increase in tone (score ≥ 3 points on the modified Ashworth scale). Participants were allowed to continue other MS medications, with the exception of benzodiazepines. Eighty percent of subjects had a history of marijuana use and 33% had used marijuana within the previous year.

Subjects participated in two 3-day test sessions, with an 11 day washout period. During each test session they smoked a 4.0% THC marijuana cigarette once per day or a placebo cigarette once per day. Smoking occurred through a standardized cued-puff procedure: (1) Inhalation for 5 seconds, (2) breath-hold and exhalation for 10 seconds, (3) pause between puffs for 45 seconds. Subjects completed an average of four puffs per cigarette.

The primary outcome measure was change in spasticity on the modified Ashworth scale. Additionally, subjects were assessed using a VAS for pain, a timed walk, and cognitive tests (Paced Auditory Serial Addition Test) and AEs.

Treatment with 4.0% THC marijuana reduced subject scores on the modified Ashworth scale by an average of 2.74 points more than placebo ($p < 0.0001$) and reduced VAS pain scores compared to placebo ($p = 0.008$). Scores on the cognitive measure decreased by 8.7 points more than placebo ($p = 0.003$). However, marijuana did not affect scores for the timed walk compared to placebo. Marijuana increased rating of feeling high compared to placebo.

7 subjects did not complete the study due to adverse events (two subjects felt uncomfortably "high", two had dizziness and one had fatigue). Of those 7 subjects who withdrew, 5 had little or no previous experience with marijuana. When the data were re-analyzed to include these drop-out subjects, with the presumption they did not have a positive response to treatment, the effect of marijuana was still significant on spasticity.

The authors conclude that smoked marijuana had usefulness in reducing pain and spasticity associated with MS. It is concerning that marijuana-naïve subjects dropped out of the study because they were unable to tolerate the psychiatric AEs induced by marijuana. The authors suggest that future studies should examine whether different doses can result in similar beneficial effects with less cognitive impact. However, the current study produced positive results suggesting that marijuana should be studied further as an adjunct treatment for spasticity in MS patients.

3.4 *Asthma*

Tashkin et al. (1974) examined bronchodilation in 10 subjects with bronchial asthma in the study entitled, "Acute Effects of Smoked Marijuana and Oral Δ^9-Tetrahydrocannabinol on Specific Airway Conductance in Asthmatic Subjects". The study was a double-blind, placebo-controlled, crossover design. All subjects were clinically stable at the time of the study; four subjects were symptom free, and six subjects had chronic symptoms of mild to moderate severity. Subjects were tested with 0.25ml of isoproterenol HCl prior to the study to ensure they responded to bronchodilator medications. Subjects were not allowed to take bronchodilator medication within 8 hours prior to the study. Previous experience with marijuana was not required for participation in the study, but 7 of the 10 subjects reported previous use of marijuana at a rate of less than 1 marijuana cigarette per month. No subjects reported marijuana use within 7 days of the study.

The study consisted of four test sessions with an interval of at least 48 hours between sessions. On two test sessions subjects smoked 7 mg/kg of body weight of either marijuana, with 2% THC concentration by weight, or placebo marijuana. During the other two test sessions, subjects ingested capsules with either 15 mg of synthetic THC or placebo. Marijuana was administered using a uniform smoking technique: subjects inhaled deeply for 2–4 seconds, held smoke in lungs for 15 seconds, and resumed normal breathing for approximately 5 seconds. The author did not provide a description of the number of puffs taken at any smoking session. The authors state that the smoking procedure was repeated until the cigarette was consumed, which took approximately 10 minutes.

The outcome measure used was specific airway conductance (SGaw), as calculated using measurements of thoracic gas volume (TGV) and airway resistance (Raw) using a variable-pressure body plethysmograph. Additionally, an assessment of degree of intoxication was administered only to those subjects reporting previous marijuana use. This assessment consisted of subjects rating "how 'high' they felt" on a scale of 0–7, 7 representing "the 'highest' they had ever felt after smoking marijuana".

Marijuana produced a significant increase of 33–48% in average SGaw compared to both baseline and placebo ($P < 0.05$). This significant increase in SGaw lasted for at least 2 hours after administration. The average TGV significantly decreased by 4–13% compared to baseline and placebo ($P < 0.05$). The author stated that all subjects reported feelings of intoxication after marijuana administration.

The authors conclude that marijuana produced bronchodilation in clinically stable asthmatic subjects with minimal to moderate bronchospasms. Study limitations include: inclusion of subjects with varying severity of asthmatic symptoms, use of SGaw to measure lung responses to marijuana administration, and administration of smoke to asthmatic subjects. Smoke delivers a number of harmful substances and is not an optimal delivery symptom, especially for asthmatic patients. FEV1 via spirometry is the gold standard to assess changes in lung function, pre and post asthma treatment, by pharmacotherapy. SGaw has been shown to be a valid tool in bronchoconstriction lung assessment; however, since the FEV1 method was not utilized, it is unclear whether these results would correlate if the FEV1 method had been employed.

3.5 Glaucoma

Two randomized, double-blind, placebo-controlled Phase 2 clinical studies examined smoked marijuana in glaucoma (Crawford and Merritt, 1979; Merritt et al., 1980). In both studies, intraocular pressure (IOP) was significantly reduced 30 minutes after smoking marijuana. Maximal effects occurred 60–90 minutes after smoking, with IOP returning to baseline within 3–4 hours. These two studies were included in the 1999 IOM report on the medical uses of marijuana. Because our independent analysis of these studies concurred with the conclusions from the 1999 IOM report, these studies will not be discussed in further detail in this review. No recent studies have been conducted examining the effect of inhaled marijuana on IOP in glaucoma patients. This lack of recent studies may be attributed to the conclusions made in the 1999 IOM report that while cannabinoids can reduce intraocular pressure (IOP), the therapeutic effects require high doses that produce short-lasting responses, with a high degree of AEs. This high degree of AEs means that the potential harmful effects of chronic marijuana smoking may outweigh its modest benefits in the treatment of glaucoma.

3.6 Conclusions

Of the eleven randomized, double-blind, placebo-controlled Phase 2 clinical studies that met the criteria for review (see Sections 2.2 and 2.3), ten studies administered marijuana through smoking, while one study utilized marijuana vaporization. In these eleven studies, there were five different therapeutic indications: five examined chronic neuropathic pain, two examined appetite stimulation in HIV patients, two examined glaucoma, one examined spasticity in MS, and one examined asthma.

There are limited conclusions that can be drawn from the data in these published studies evaluating marijuana for the treatment of different therapeutic indications. The analysis relied on published studies, thus information available about protocols, procedures, and results were limited to documents published and widely available in the public domain. The published studies on medical marijuana are effectively proof-of-concept studies. Proof-of-concept studies provide preliminary evidence on a proposed hypothesis regarding a drug's effect. For drugs under development, the effect often relates to a short-term clinical outcome being investigated. Proof-of-concept studies serve as the link between preclinical studies and dose ranging clinical studies. Therefore, proof-of-concept studies are not sufficient to demonstrate efficacy of a drug because they provide only preliminary information about the effects of a drug. Although these studies do not provide evidence that marijuana is effective in treating a specific, recognized disorder, these studies do support future larger well-controlled studies to assess the safety and efficacy of marijuana for a specific medical indication. Overall, the conclusions below are preliminary, based on very limited evidence.

3.6.1 Conclusions for Chronic Neuropathic Pain

In subjects with chronic neuropathic pain who are refractory to other pain treatments, five proof-of-concept studies produced positive results regarding the use of smoked marijuana for analgesia. However, the subjects in these studies continued to use their current analgesic drug regime, and thus no conclusions can be made regarding the potential efficacy of marijuana for neuropathic pain in patients not taking other analgesic drugs. Subjects also had numerous forms of neuropathic pain, making it difficult to identify whether a specific set of symptoms might be more responsive to the effects of marijuana. It is especially concerning that some marijuana-naïve subjects had intolerable psychiatric responses to marijuana exposure at analgesic doses.

3.6.2 Conclusions for Appetite Stimulation in HIV

In subjects who were HIV-positive, two proof-of-concept studies produced positive results with the use of both dronabinol and smoked marijuana to increase caloric intake and produce weight gain in HIV-positive patients. However, the amount of THC in the marijuana tested in these studies is four times greater than the dose of dronabinol typically tested for appetite stimulation (10 mg vs. 2.5 mg; Haney et al., 2005). Thus, it is possible that the low degree of AEs reported in this study may reflect the development of tolerance to cannabinoids in this patient population, since all individuals had current histories of chronic marijuana use. Thus, individuals with little prior exposure to marijuana may not respond similarly and may not be able to tolerate sufficient marijuana to produce appetite stimulation.

3.6.3 Conclusions for Spasticity in MS

In subjects with MS, a proof of concept study produced positive results using smoked marijuana as a treatment for pain and symptoms associated with treatment-resistant spasticity. The subjects in this study continued to take their current medication regiment, and thus no conclusions can be made regarding the potential efficacy of marijuana when taken on its own. It is also concerning that marijuana-naïve subjects dropped out of the study because they were unable to tolerate the psychiatric AEs induced by marijuana. The authors suggest that future studies should examine whether different doses can result in similar beneficial effects with less cognitive impact.

3.6.4 Conclusions for Asthma

In subjects with clinically stable asthma, a proof of concept study produced positive results of smoked marijuana producing bronchodilation. However, in this study marijuana was administered at rest and not while experiencing bronchospasms. Additionally, the administration of marijuana through smoking introduces harmful and irritating substances to the subject, which is undesirable especially in asthmatic patients. Thus the results suggest marijuana may have bronchodilator effects, but it may also have undesirable adverse effects in subjects with asthma.

3.6.5 Conclusions for Glaucoma

As noted in Sections 3.5, the two studies that evaluated smoked marijuana for glaucoma were conducted decades ago, and they have been thoroughly evaluated in the 1999 IOM report. The 1999 IOM report concludes that while the studies with marijuana showed positive results for reduction in IOP, the effect is short-lasting, requires a high dose, and is associated with many AEs. Thus, the potential harmful effects may outweigh any modest benefit of marijuana for this condition. We agree with the conclusions drawn in the 1999 IOM report.

3.7 Design Challenges for Future Studies

The positive results reported by the studies discussed in this review support the conduct of more rigorous studies in the future. This section discusses methodological challenges that have occurred in clinical studies with smoked marijuana. These design issues should be addressed when larger-scale clinical studies are conducted to ensure that valid scientific data are generated in studies evaluating marijuana's safety and efficacy for a particular therapeutic use.

3.7.1 Sample Size

The ability for results from a clinical study to be generalized to a broader population is reliant on having a sufficiently large study sample size. However, as noted above, all of the 11 studies reviewed in this document were early Phase 2 proof of concept studies for efficacy and safety. Thus, the sample sizes used in these studies were inherently small, ranging from 10 subjects per treatment group (Tashkin et al., 1974; Haney et al., 2007) to 25 subjects per treatment group (Abrams et al., 2007). These sample sizes are statistically inadequate to support a showing of safety or efficacy. FDA's recommendations about sample sizes for clinical trials can be found in the *Guidance for Industry: E9 Statistical Principles for Clinical Trials (1998).*[35] For example, ''the number of subjects in a clinical trial should always be large enough to provide a reliable answer to the questions addressed. This number is usually determined by the primary objective of the trial. The method by which the sample size is calculated should be given in the protocol, together with the estimates of any quantities used in the calculations (such as variances, mean values, response rates, event rates, difference to be detected).'' (pg. 21). Other clinical FDA *Guidance for Industry*[36] may also contain recommendations regarding the appropriate number of subjects that should be investigated for a specific medical indication.

3.7.2 Marijuana Dose Standardization

Dose standardization is critical for any clinical study in order to ensure that each subject receives a consistent exposure to the test drug. The *Guidance for Industry: Botanical Drug Products* (2004)[37] provides specific information on the development of botanical drug products. Specifically, this guidance includes information about the need for well-characterized and consistent chemistry for the botanical plant product and for consistent and reliable dosing. Specifically for marijuana studies, dose standardization is important because if marijuana leads to plasma levels of cannabinoids that are significantly different between subjects, this variation may lead to differences in therapeutic responsivity or in the prevalence of psychiatric AEs.

In most marijuana studies discussed in this review, investigators use a standardized cued smoking procedure. In this procedure, a subject is instructed to inhale marijuana smoke for 5 seconds, hold the smoke in the lungs for 10 seconds, exhale and breathe normally for 40 seconds. This process is repeated to obtain the desired dose of the drug. However, this procedure may not lead to equivalent exposure to marijuana and its constituent cannabinoids, based on several factors:

- Intentional or unintentional differences in the depth of inhalation may change the amount of smoke in the subject's lungs.
- Smoking results in loss from side stream smoke, such that the entire dose is not delivered to the subject.
- There may be differences in THC concentration along the length of a marijuana cigarette. According to Tashkin et al. (1991), the area of the cigarette closest to the mouth tends to accumulate a higher concentration of THC, but this section of the cigarette is not smoked during a study.

For example, Wilsey et al. (2008) used this standardized smoking procedure. The reported mean (range) of marijuana cigarettes consumed was 550 mg (200–830mg) for the low strength marijuana (3.5% THC) and 490 mg (270–870mg) for the high strength marijuana (7% THC). This wide range of amounts of marijuana cigarette smoked by the individual subjects, even with standardized smoking procedure and controlled number of puffs, supports the issues with delivering consistent doses with smoke marijuana.

In other marijuana studies that do not use a cued smoking procedure, subjects are simply told to smoke the marijuana cigarette over a specific amount of time (usually 10 minutes) without further instruction (Crawford and Merritt, 1979; Merritt et al., 1980; Ellis et al., 2009). The use of a nonstandardized procedure may lead to non-equivalent exposures to marijuana and its constituent cannabinoids between subjects because of additional factors that are not listed above, such as:

- Differences in absorption and drug response if subjects (especially marijuana-naïve ones) are not instructed to hold marijuana smoke in their lungs for a certain period of time.

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[35] The *Guidance for Industry: E9 Statistical Principles for Clinical Trials* can be found at: *www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073137.pdf.*

[36] Other Guidances for Industry can be found at: *www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm064981.htm.*

[37] The *Guidance for Industry: Botanical Drug Products* can be found at: *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070491.pdf.*

- Prolonged periods between puffs may increase loss to side stream smoke.
- Subjects may attempt to smoke the marijuana cigarette in the way they would smoke a tobacco cigarette, which relies primarily on short, shallow puffs.

In both standardized and non-standardized smoking procedures, subjects may seek to control the dose of THC through self-titration (Crawford and Merritt, 1979; Merritt et al., 1980; Tashkin et al., 1974; Abrams et al., 2007; Ellis et al., 2009). Self-titration involves an individual moderating the amount of marijuana smoke inhaled over time in order to obtain a preferred level of psychoactive or clinical response. The ability of an individual to self-titrate by smoking is one reason given by advocates of "medical marijuana" in support of smoking of marijuana rather than through its ingestion via edibles. However, for research purposes, self-titration interferes with the ability to maintain consistent dosing levels between subjects, and thus, valid comparisons between study groups.

All of these factors can make the exact dose of cannabinoids received by a subject in a marijuana study difficult to determine with accuracy. Testing whether plasma levels of THC or other cannabinoids are similar between subjects following the smoking procedure would establish whether the procedure is producing appropriate results. Additionally, studies could be conducted to determine if vaporization can be used to deliver consistent doses of cannabinoids from marijuana plant material. Specifically, vaporization devices that involve the collection of vapors in an enclosed bag or chamber may help with delivery of consistent doses of marijuana. Thus, more information could be collected on whether vaporization is comparable to or different than smoking in terms of producing similar plasma levels of THC in subjects using identical marijuana plant material.

3.7.3 Acute vs. Chronic Therapeutic Marijuana Use

The studies that were reviewed administered the drug for short durations lasting no longer than 5 days (Abrams et al., 2007; Ellis et al., 2009; Ware et al., 2010). Thus all studies examined the short-term effect of marijuana administration for therapeutic purposes. However, many of the medical conditions that have been studied are persistent or expected to last the rest of a patient's life. Therefore, data on chronic exposure to smoked marijuana in clinical studies is needed. In this way, more information will be available regarding whether tolerance, physical dependence, or specific adverse events develop over the course of time with continuing use of therapeutic marijuana.

3.7.4 Smoking as a Route of Administration

As has been pointed out by the IOM and other groups, smoking is not an optimum route of administration for marijuana-derived therapeutic drug products, primarily because introducing the smoke from a burnt botanical substance into the lungs of individuals with a disease state is not recommended when their bodies may be physically compromised. The 1999 IOM report on medicinal uses of marijuana noted that alternative delivery methods offering the same ability of dose titration as smoking marijuana will be beneficial and may limit some of the possible long-term health consequences of smoking marijuana. The primary alternative to smoked marijuana is vaporization, which can reduce exposure to combusted plant material containing cannabinoids. The only study to use vaporization as the delivery method was Wilsey et al. (2013). The results from Wilsey et al. (2013) showed a similar effect of decreased pain as seen in the other studies using smoking as the delivery method (Ware et al., 2010; Wilsey et al., 2008). This similar effect of decrease pain supports vaporization as a possibly viable route to administer marijuana in research, while potentially limiting the risks associated with smoking.

3.7.5 Difficulty in Blinding of Drug Conditions

An adequate and well-controlled clinical study involves double-blinding, where both the subjects and the investigators are unable to tell the difference between the test treatments (typically consisting of at least a test drug and placebo) when they are administered. All of the studies reviewed in this document administered study treatments under double-blind conditions and thus were considered to have an appropriate study design.

However, even under the most rigorous experimental conditions, blinding can be difficult in studies with smoked marijuana because the rapid onset of psychoactive effects readily distinguishes active from placebo marijuana. The presence of psychoactive effects also occurs with other drugs. However, most other drugs have a similar psychoactive effect with substances with similar mechanisms of actions. These substances can be used as positive controls to help maintain blinding to the active drug being tested. Marijuana on the other hand, has a unique set of psychoactive effects which makes the use of appropriate positive controls difficult (Barrett et al., 1995). However, two studies did use Dronabinol as a positive control drug to help maintain blinding (Haney et al., 2005; Haney et al., 2007).

When blinding is done using only placebo marijuana, the ability to distinguish active from placebo marijuana may lead to expectation bias and an alteration in perceived responsivity to the therapeutic outcome measures. With marijuana-experienced subjects, for example, there may be an early recognition of the more subtle cannabinoid effects that can serve as a harbinger of stronger effects, which is less likely to occur with marijuana-naïve subjects. To reduce this possibility, investigators have tested doses of marijuana other than the one they were interested in experimentally to maintain the blind (Ware et al., 2010).

Blinding can also be compromised by differences in the appearance of marijuana plant material based on THC concentration. Marijuana with higher concentrations of THC tends to be heavier and seemingly darker, with more "tar-like" substance. Subjects who have experience with marijuana have reported being able to identify marijuana from placebo cigarettes by sight alone when the plant material in a cigarette was visible (Tashkin et al., 1974; Ware et al., 2010). Thus, to maintain a double-blind design, many studies obscure the appearance of plant material by closing both ends of the marijuana cigarette and placing it in in an opaque plastic tube.

While none of these methods to secure blinding may be completely effective, it is important to reduce bias as much as possible to produce consistent results between subjects under the same experimental conditions.

3.7.6 Prior Marijuana Experience

Marijuana use histories in test subjects may influence outcomes, related to both therapeutic responsivity and psychiatric AEs. Marijuana-naïve subjects may also experience a marijuana drug product as so aversive that they would not want to use the drug product. Thus, subjects' prior experience with marijuana may affect the conduct and results of studies.

Most of the studies reviewed in this document required that subjects have a history of marijuana use (see tables in Appendix that describe specific requirements for each study). However, in studies published in the scientific literature, the full inclusion criteria with regard to specific amount of experience with marijuana may not be provided. For those studies that do provide inclusion criteria, acceptable experience with marijuana can range from once in a lifetime to use multiple times a day.

The varying histories of use might affect everything from scores on adverse event measures, safety measures, or efficacy measures. Additionally, varying amounts of experience can impact cognitive effect measures assessed during acute administration studies. For instance, Schreiner and Dunn (2012) contend cognitive deficits in heavy marijuana users continue for approximately 28 days after cessation of smoking. Studies requiring less than a month of abstinence prior to the study may still see residual effects of heavy use at baseline and after placebo marijuana administration, thus showing no significant effects on cognitive measures. However, these same measurements in occasional or naïve marijuana users may demonstrate a significant effect after acute marijuana administration. Therefore, the amount of experience and the duration of abstinence of marijuana use are important to keep in mind when analyzing results for cognitive and other adverse event measures. Lastly, a study population with previous experience with marijuana may underreport the incidence and severity of adverse events. Because most studies used subjects with prior marijuana experience, we are limited in our ability to generalize the results, especially for safety measures, to marijuana naïve populations.

Five of 11 studies reviewed in this document included both marijuana-naïve and marijuana-experienced subjects (Corey-Bloom et al., 2012; Ellis et al., 2009; Ware et al., 2010; Merritt et al., 1980; Tashkin et al., 1974). Since the number of marijuana-naïve subjects in these studies was low, it was not possible to conduct a separate analysis compared to experienced users. However, systematically evaluating the effect of marijuana experience on study outcomes is important, since many patients who might use a marijuana product for a therapeutic use will be marijuana-naïve.

Research shows that marijuana-experienced subjects have a higher ability to tolerate stronger doses of oral dronabinol than marijuana-naïve subjects (Haney et al., 2005). Possibly, this increased tolerance is also the case when subjects smoke or vaporize marijuana. Thus, studies could be conducted that investigate the role of marijuana experience in determining tolerability of and responses to a variety of THC concentrations in marijuana.

3.7.7 Inclusion and Exclusion Criteria

For safety reasons, all clinical studies have inclusion and exclusion criteria that restrict the participation of individuals with certain medical conditions. For studies that test marijuana, these criteria may be based on risks associated with exposure to smoked material and the effects of THC. Thus, most studies investigating marijuana require that subjects qualify for the study based on restrictive symptom criteria such that individuals do not have other symptoms that may be known to interact poorly with cannabinoids.

Similarly, clinical studies with marijuana typically exclude individuals with cardiac or pulmonary problems, as well as psychiatric disorders. These exclusion criteria are based on the well-known effects of marijuana smoke to produce increases in heart rate and blood pressure, lung irritation, and the exacerbation of psychiatric disturbances in vulnerable individuals. Although these criteria are medically reasonable for research protocols, it is likely that future marijuana products will be used in patients who have cardiac, pulmonary or psychiatric conditions. Thus, individuals with these conditions should be evaluated, whenever possible.

Additionally, all studies reviewed in this document allowed the subjects to continue taking their current regimen of medications. Thus all results evaluated marijuana as an adjunct treatment for each therapeutic indication.

3.7.8 Number of Female Subjects

A common problem in clinical research is the limited number of females who participate in the studies. This problem is present in the 11 studies reviewed in this document, in which one study did not include any female subjects (Ellis et al., 2009), and three studies had a low percentage of female subjects (Abrams et al., 2007; Haney et al., 2005; Haney et al., 2007). However, each of these four studies investigated an HIV-positive patient population, where there may have been a larger male population pool from which to recruit compared to females.

Since there is some evidence that the density of CB1 receptors in the brain may vary between males and females (Crane et al., 2012), there may be differing therapeutic or subjective responsivity to marijuana. Studies using a study population that is equal parts male and female may show whether and how the effects of marijuana differ between male and female subjects.

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Appendix (Tables)

Table 1: Randomized, controlled, double-blind trials examining smoked marijuana in treatment of neuropathic pain

Author & Date *Indication*	**Subjects (n) completed/randomized Subject characteristics**	**Drugs Admin. Methods**	**Study Type** *Duration*	**Primary Outcome Measure**	**Primary Outcome Measure Results**	**Adverse events/AEs**
Abrams et al. (2007) *HIV-Sensory Neuropathy; Neuropathic Pain*	Marijuana Group: 25/27 22 males 5 females Placebo Group: 25/28 26 males 2 females Inclusion Criteria: -documented HIV -documented HIV-SN -pain score ≥30mm VAS -prior marijuana use of six or more times in lifetime Previous Marijuana Experience: -marijuana group: 21 current users -placebo group: 19 current users Exclusion Criteria: -substance abuse (including tobacco) -family history of neuropathy due to causes not HIV related -use of isoniazid,	NIDA marijuana, smoked 0%, 3.65% THC Smoking Procedure: -signal light cued smoking of marijuana cigarette with each puff consisting of: 1) 5s inhale smoke, 2) 10s hold smoke in lungs 3) 40s exhale and breath normally 4) repeat procedure for desired number of puffs # of puffs not specified, only specified that subjects smoked the entire marijuana/placebo cigarette On 1st and last day of intervention period BID. For all other days TID	Parallel Group *5-day treatment period*	VAS daily pain score	-52% of the marijuana group showed >30% decrease in pain score compared to 24% of placebo group. -Marijuana group had significantly greater reduction in daily pain score than placebo group. -NNT=3.6	-Rating for adverse events of anxiety, sedation, disorientation, confusion, and dizziness were significantly higher in the marijuana group compared to placebo group. -Marijuana and placebo groups showed a reduction in total mood disturbance on POMS. AEs: -1 grade 3 dizziness in marijuana group -2 grade 3 anxiety, 1 in each group.

Author & Date *Indication*	**Subjects (n) completed/randomized Subject characteristics**	**Drugs Admin. Methods**	**Study Type** *Duration*	**Primary Outcome Measure**	**Primary Outcome Measure Results**	**Adverse events/AEs**
	dapsone, or metronidazole within 8 weeks of enrollment					
Ellis et al. (2009) *HIV Sensory Neuropathy; Neuropathic Pain*	28/34 28 males Inclusion Criteria: -documented HIV -documented neuropathic pain refractory to ≥2 analgesics -pain score ≥5 on pain intensity subscale of DDS Previous Marijuana Experience: -27 subjects had previous experience -63% of subjects had no exposure for >1 year before study Exclusion Criteria: -current DSM-IV substance abuse disorder -lifetime history of dependence on marijuana -previous psychosis with or intolerance to cannabinoids -concurrent use of approved cannabinoid medications -positive UDS for	NIDA marijuana, smoked 0%, 1%, 2%, 4%, 6%, 8% THC Smoking Procedures: - Verbally cued smoking of marijuana cigarette with each puff consisting of: 1) 5s inhale smoke, 2) 10s hold smoke in lungs 3) 40s exhale and breath normally 4) repeat procedure for desired number of puffs -unknown number of puffs QID	Crossover Dose-titration (on 1st day) *2, 5-day treatment phase, with 2-week washout period*	Pain magnitude on DDS	-Pain reduction was significantly greater after marijuana compared to placebo. -NNT=3.5	-Mood disturbance, quality of life, and psychical disability improved for both marijuana and placebo. -Moderate to severe adverse events were more common with marijuana than placebo. -HIV disease parameters did not differ for marijuana or placebo. -Adverse events included: concentration difficulties, fatigue, sleepiness or sedation, increased duration of sleep, reduced salivation, and thirst. These adverse events were more frequent in marijuana compared to placebo. Withdrawals for drug related reasons: -1 cannabis-naïve subject had acute cannabis-induced psychosis -1 subjects developed an intractable smoking-related cough during marijuana administration

Author & Date *Indication*	**Subjects (n) completed/randomized Subject characteristics**	**Drugs Admin. Methods**	**Study Type** ***Duration***	**Primary Outcome Measure**	**Primary Outcome Measure Results**	**Adverse events/AEs**
	cannabinoids during wash-in week -serious medical conditions that affect safety -alcohol or drug dependence within 12 months of study					
Wilsey et al. (2008) *Neuropathic pain: Various Causes*	32/38 20 males 18 females Inclusion Criteria: -CRPS type I, spinal cord injury, peripheral neuropathy, or nerve damage -previous marijuana use Previous Marijuana Experience: -median (range) time from previous exposure: 1.7 years (31 days to 30 years) -median (range) exposure duration: 2 years (1 day to 22 years). Exclusion Criteria: -no marijuana or cannabinoid medication use for 30 days prior to study; confirmed by UDS	NIDA marijuana, smoked 0%, 3.55%, 7% THC Smoking Procedure: Verbally cued smoking of marijuana cigarette with each puff consisting of: 1) 5s inhale smoke, 2) 10s hold smoke in lungs 3) 40s exhale and breath normally 4) repeat procedure for desired number of puffs Cumulative dosing procedure: -escalate the number of puffs from 2 to 4 puffs over 3 smoking sessions with 1 hour between sessions	Crossover *3, 6-hour sessions, with 3-day between sessions*	VAS spontaneous pain intensity	-A significant decrease in pain intensity for both strengths of marijuana compared to placebo	-7% THC marijuana significantly decreased functioning on neurocognitive measures compared to placebo. -Subjective effects were greater for 7% THC marijuana than 3.55% THC marijuana with significantly more ratings of good drug effect, bad drug effect, feeling high, feeling stoned, impaired, sedation, confusion, and hunger compared to placebo.

Author & Date *Indication*	**Subjects (n) completed/randomized Subject characteristics**	**Drugs Admin. Methods**	**Study Type** *Duration*	**Primary Outcome Measure**	**Primary Outcome Measure Results**	**Adverse events/AEs**
	-severe depression -history of schizophrenia or bipolar depression -uncontrolled hypertension, cardiovascular disease, and pulmonary disease -active substance abuse	TID				
Ware et al. (2010) *Post-traumatic or postsurgical neuropathic pain*	21/23 11 males 12 females Inclusion Criteria: -neuropathic pain for ≥ 3 months caused by trauma or surgery -allodynia and hyperalgesia -pain score >4cm VAS -no marijuana use for 1 year prior to study -stable analgesic regimen -normal liver and renal function Previous Marijuana Experience: -18 subjects had used marijuana before Exclusion Criteria: -pain due to cancer or nociceptive causes -significant cardiac or	NIDA placebo; Prairie Plant System Inc. (Canada) marijuana, smoked 0%, 2.5%, 6%, 9.4% THC (25 mg of marijuana/placebo plant material was placed in opaque gelatin capsules) Smoking Procedures: -1) Break one capsule open and tip content into the bowl of a titanium pipe 2) light marijuana material 3) 5s inhale smoke 4) 10s hold smoke in lungs 5) Exhale 1 puff burned all 25 mg of plant material	Crossover *4, 5-day out-patient* treatment phase, with 9-day washout periods*	Pain intensity on 11-item NRS	-Average daily pain intensity was significantly lower after 9.4% THC compared to placebo.	-Anxiety and depression were significantly improved with 9.4% THC compared to placebo. -No significant difference between placebo and 9.4% THC for subjective effects. AEs: -248 mild AEs were reported -6 moderate AEs were reported: 2 fall, 1 increased pain, 1 numbness, 1 drowsiness, 1 pneumonia -Most frequently reported drug-related AEs for 9.4% THC: headache, dry eyes, burning sensation, dizziness, numbness, and cough. Withdrawals for drug related reason: -1 subject had increased pain after 6% THC administration -1 subject tested positive for cannabinoids in urine test during placebo treatment

Author & Date *Indication*	**Subjects (n) completed/randomized Subject characteristics**	**Drugs Admin. Methods**	**Study Type** ***Duration***	**Primary Outcome Measure**	**Primary Outcome Measure Results**	**Adverse events/AEs**
	pulmonary disease -current substance abuse or dependence (including marijuana) -history of psychotic disorders -current suicidal ideations	TID Intermediate doses were used to help maintain blinding				
Wilsey et al. (2013) *Neuropathic Pain: Various Causes*	36/39 28 males 11 females Inclusion Criteria: -CRPS type 1, thalamic pain, spinal cord injury, peripheral neuropathy, radiculopathy, or nerve injury -previous marijuana use Previous Marijuana Experience: - median (range) time from last exposure prior to screening: 9.6 years (1 day to 45 years) -16 current marijuana users and 23 past users -# smoked daily: 6 current users, 5 past users -# used approx. once every 2 weeks: 8 current users, 6 past users -# used once every 4 weeks or less: 2 current	NIDA marijuana, vaporized 0%, 1.29%, 3.53% THC Smoking Procedures: - Verbally cued inhalation of vaporized material in the balloon with each puff consisting of: 1) 5s inhale vapors, 2) 10s hold vapors in lungs 3) 40s exhale and breath normally 4) repeat procedure for desired number of puffs BID Cumulative & Flexible Dosing: -1st drug admin. consisted of 4 puffs from balloon.	Crossover *3, 6-hour sessions, with at least 3 days between sessions*	VAS spontaneous pain intensity	-Number of subjects that showed a 30% reduction in pain intensity was significantly greater for both strengths of marijuana compared to placebo. -Both strengths of marijuana showed a similar significant decrease in pain compared to placebo. -NNT=3.2 for 1.29% THC marijuana vs. placebo. -NNT=2.9 for 3.53% THC marijuana vs. placebo.	-Scores for feeling stoned, feeling high, like the drug effect, feeling sedated, and feeling confused were significantly greater for 3.53% THC marijuana compared to 1.29% THC marijuana, and for both strengths of marijuana compared to placebo. -Scores for feeling drunk and feeling impaired are significantly greater in both strengths of marijuana compared to placebo. -Scores for desired more of the drug were significantly greater for 1.29% THC marijuana compared to placebo, with no significant difference seen for 3.53% THC marijuana. -3.53% THC marijuana had significantly worse performance than 1.29% THC marijuana for learning and memory. -Both strengths of marijuana significantly reduced scores on attention compared to placebo.

Author & Date *Indication*	**Subjects (n) completed/randomized Subject characteristics**	**Drugs Admin. Methods**	**Study Type** *Duration*	**Primary Outcome Measure**	**Primary Outcome Measure Results**	**Adverse events/AEs**
	users, 12 past users Exclusion Criteria: -no marijuana or cannabinoid medication use for 30 days prior to study; confirmed by UDS -severe depression -suicidal ideations -diagnoses of serious mental illness -uncontrolled hypertension, cardiovascular disease, or chronic pulmonary disease -active substance abuse	-Followed 2 hours later by 2nd drug admin. -2nd drug admin. consisted of 4 to 8 puffs from balloon; number of puffs taken was left up to the subject so they could self-titrate to their target does, which balanced desired response and tolerance levels.				

*Out-patient: subjects were given enough doses of marijuana/placebo to last the 5-day treatment phase, and then were sent home for the remainder of the treatment phase. AE=Adverse Event; BID=drug administered two times per day; CRPS=complex regional pain syndrome; DDS=Descriptor Differential Scale; NIDA=National Institute of Drug Abuse; NNT=Number Needed to Treat; NRS=Numeric Rating Scale; QID=drug administered four times per day; THC=delta-9-tetrahydrocannbinol; TID=drug administered three times per day; UDS=urine drug screen; VAS=Visual Analog Scale.

Table 2: Randomized, controlled, double-blind trials examining smoked marijuana in treatment of appetite stimulation in HIV/AIDS

Author & Date ***Indication***	**Subjects (n) completed/randomized Subject characteristics**	**Drugs Admin. Methods**	**Study Type** ***Duration***	**Primary Outcome Measure**	**Results (summary)**	**Adverse events/AEs**
Haney et al. (2005) *HIV+ with either normal muscle mass (Normal-BIA) or clinically significant loss of muscle mass (Low-BIA)*	Low-BIA: 15/17 12 males 3 females Normal-BIA: 15/18 15 males Inclusion Criteria: -21-50 years of age -prescribed at least 2 antiretroviral medications -currently under the care of a physician for HIV management -medically and psychiatrically stable -smoke marijuana ≥ 2x/week for past 4 weeks Previous Marijuana Experience: -mean (SD) # of days/week of marijuana use: Low-BIA= 6 (2); Normal-BIA=5 (2) -mean (SD) # marijuana cigarettes/day: Low-BIA=3 (2); Normal-BIA=3 (1) -mean (SD) years of marijuana use: Low-BIA=12.2 (8.3);	NIDA marijuana, smoked 0%, 1.8%, 2.8%, 3.9% THC Dronabinol, oral 0, 10, 20, 30mg Double-dummy drug admin. Procedures: -only 1 active dose per session -one dronabinol/placebo capsule followed 1 hour later by marijuana/placebo smoking Smoking Procedures: Verbally cued smoking of marijuana cigarette with each puff consisting of: 1) 5s inhale smoke, 2) 10s hold smoke in lungs 3) 40s exhale and breath normally	Crossover *8, 7-hour session, with at least 1 day between sessions*	No primary outcome measure is specified Related outcome measure was caloric intake	-In Low-BIA all dronabinol doses and 1.8% and 3.9% THC marijuana significantly increased caloric intake compared with placebo.	-Ratings of high and good drug effect were significantly increased for all strengths of marijuana and all doses of dronabinol except 10mg dronabinol. -3.9% THC significantly increased ratings of dry mouth and thirsty compared to placebo. -Low-BIA group showed no significant adverse event ratings, and in the normal-BIA group the only significant adverse events in response to marijuana included: diarrhea after 3.9% THC marijuana. -Dronabinol had more incidences of adverse events at all doses compared to marijuana.

Author & Date *Indication*	**Subjects (n) completed/randomized Subject characteristics**	**Drugs Admin. Methods**	**Study Type** *Duration*	**Primary Outcome Measure**	**Results (summary)**	**Adverse events/AEs**
	Normal-BIA=10.8 (2.6) Exclusion Criteria: -diagnosis of nutritional malabsorption, major depression, dementia, chronic diarrhea, weakness, fever, significant pulmonary disease -an opportunistic infection within past 3 months -obesity -use of steroids within past 3 weeks -drug dependence (excluding marijuana or nicotine)	4) repeat for 3 puffs per smoking session QD				
Haney et al. (2007) *HIV+*	10 9 males 1 female Inclusion Criteria: -21-50 years of age -taking ≥ 2 antiretroviral medications -under the care of a physician for HIV management -medically and psychiatrically stable -smoke marijuana ≥	NIDA marijuana, smoked 0%, 2%, 3.9% THC Dronabinol, oral 0, 5, 10mg Double-dummy drug admin. Procedures: -only 1 active dose per session -one dronabinol/placebo	Crossover *2, 16-day treatment phases, with 5-10 days between phases* *Each 16-day treatment phase consisted of 2, 4-day active drug*	No primary outcome measure is specified Related outcome measures were Caloric Intake & Body Weight	-Both strengths of marijuana significantly increased caloric intake compared to placebo. -3.9% THC marijuana significantly increased body weight compared to placebo.	-Both strengths of marijuana significantly increased ratings of: good drug effect, high, mellow, stimulate, friendly, and self-confident. Only 2% THC marijuana significantly increased ratings of anxious. -Both strengths of marijuana significantly increased subjective measures for satisfied sleep and estimated time of sleep.

Author & Date *Indication*	**Subjects (n) completed/randomized Subject characteristics**	**Drugs Admin. Methods**	**Study Type** *Duration*	**Primary Outcome Measure**	**Results (summary)**	**Adverse events/AEs**
	2x/week for the past 4 weeks Previous Marijuana Experience: -mean (SD) # of days/week of marijuana use: 4.6 (0.6) -mean (SD) # marijuana cigarettes/day: 3.2 (0.8) -mean (SD) years of marijuana use: 18.6 (3.3) Exclusion Criteria: -diagnosis of nutritional malabsorption, major depression, dementia, chronic diarrhea, weakness, fever, significant pulmonary disease -an opportunistic infection within past 3 months -obesity -use of steroids within past 3 weeks -drug dependence (excluding marijuana or nicotine)	capsule followed 1 hour later by marijuana/placebo smoking Smoking Procedures: Light cued smoking of marijuana cigarette with each puff consisting of: 1) 5s inhale smoke, 2) 10s hold smoke in lungs 3) 40s exhale and breath normally 4) repeat for 3 puffs per smoking session QID	*period with 4-day placebo period between active drug periods.*			

AE=Adverse Event; BIA=Bioelectric Impedance Analysis; NIDA=National Institute of Drug Abuse; QD=drug administered one time per day; QID=drug administered four times per day; THC=delta-9-tetrahydrocannbinol

Table 3: **Randomized, controlled, double-blind trails examining smoked marijuana in treatment of spasticity in Multiple Sclerosis**

Author & Date *Indication*	**Subjects (n) completed/randomized Subject characteristics**	**Drugs Admin. Methods**	**Study Type** *Duration*	**Primary Outcome Measure**	**Primary Outcome Measure Results**	**Adverse events/AEs**
Corey-Bloom et al. (2012) *Multiple Sclerosis; Spasticity*	30/37 11 males 19 females Inclusion Criteria: -documented MS -spasticity -moderate increase in tone (score ≥ 3 on modified Ashworth scale Previous Marijuana Experience: -24 subjects had previous exposure to marijuana -10 subjects used marijuana within the year Exclusion Criteria: -no marijuana smoking for ≤1 month prior to screening -psychiatric disorder (other than depression) -history of substance use -substantial neurological disease other than MS -severe or unstable	NIDA marijuana, smoked 0%, 4% THC Smoking Procedure: smoking of marijuana cigarette with each puff consisting of: 1) 5s inhale smoke, 2) 10s hold smoke in lungs 3) 45s exhale and breath normally 4) repeat for an average of 4 puffs per smoking session QD	Crossover *2, 3-day treatment periods, with 11 day washout period*	Spasticity on the Modified Ashworth Scale	-Smoking marijuana significantly reduced spasticity scores compared to placebo	-Marijuana reduced scores on cognitive measure compared to placebo. -Marijuana significantly increased perceptions of "highness" compared to placebo Withdrawals for drug-related reasons: -2 subjects felt uncomfortably high -2 dizziness -1 fatigue

Author & Date *Indication*	**Subjects (n) completed/randomized Subject characteristics**	**Drugs Admin. Methods**	**Study Type** *Duration*	**Primary Outcome Measure**	**Primary Outcome Measure Results**	**Adverse events/AEs**
	medical illnesses -known pulmonary disorders -using high dose narcotic medication for pain -using benzodiazepines to control spasticity					

AE=Adverse Event; MS= Multiple Sclerosis; NIDA=National Institute of Drug Abuse; QD=drug administered one time per day; THC=delta-9-tetrahydrocannbinol

Table 4: Randomized, controlled, double-blind trails examining smoked marijuana in treatment of intraocular pressure in Glaucoma

Author & Date *Indication*	**Subjects (n) completed/randomized Subject characteristics**	**Drugs Admin. Methods**	**Study Type** *Duration*	**Primary Outcome Measure**	**Results (summary)**	**Adverse events/AEs**
Crawford & Merritt (1979) *Hypertensive and Normotensive Glaucoma*	HT group: 8 4 males 4 females NT group: 8 4 males 4 females Inclusion Criteria: -documented glaucoma Previous Marijuana Experience: -all were marijuana naïve Exclusion Criteria: -coronary artery disease	NIDA marijuana, smoked 0%, 2.8% THC Smoking Procedure: -instructed to inhale 20 times deeply and retain smoke in lungs -smoke marijuana/placebo cigarette in 5 minutes QD	Crossover *4, 1-day sessions, no time between sessions*	No primary outcome measure is specified Related outcome measure was IOP	-Marijuana decreased IOP by 37-44% from baseline. -The maximal decrease in IOP was significantly greater in HT (-14mmHg) than NT (-9mmHg) after marijuana .	-Placebo marijuana increased heart rate for 10 minutes in both groups. -The maximal increase in heart rate was significantly greater in NT than HT after marijuana. -The maximal decrease in blood pressure was significantly greater in HT than NT after marijuana.
Merritt et al. (1980) *Glaucoma*	18 12 males 6 females (31 glaucoma eyes, analyzed results for each eye) Inclusion Criteria: -documented glaucoma Previous Marijuana Experience: -9 subjects had used marijuana at least once Exclusion Criteria:	NIDA marijuana, smoked 0%, 2% THC Smoking Procedure: -None described -smoked 1 marijuana/placebo cigarette over 10-20 minutes QD	Crossover *2, 1-day sessions*	No primary outcome measure is specified Related outcome measure was IOP	-Marijuana significantly decreased IOP compared to placebo	-Marijuana significantly increased heart rate compared to placebo -Blood pressure significantly decreased after marijuana -All subjects experienced hunger, thirst, euphoria, drowsy, and feeling cold -Observed adverse events were greater in marijuana naïve subjects than in subjects with prior marijuana experience. AEs: -5 subjects postural hypotension

Author & Date *Indication*	**Subjects (n) completed/randomized Subject characteristics**	**Drugs Admin. Methods**	**Study Type** *Duration*	**Primary Outcome Measure**	**Results (summary)**	**Adverse events/AEs**
	-cardiac, neurological, and psychiatric dysfunction					-8 subjects anxiety with tachycardia and palpitations

AE=Adverse Event; HT=Hypertensive; IOP=Intraocular pressure; NIDA=National Institute of Drug Abuse; NT=Normotensive; QD=drug administered one time per day; THC=delta-9-tetrahydrocannbinol

Table 5: Randomized, controlled, double-blind trails examining smoked marijuana in treatment of asthma

Author & Date *Indication*	**Subjects (n) completed/randomized Subject characteristics**	**Drugs Admin. Methods**	**Study Design** *Duration*	**Primary Outcome Measure**	**Results (summary)**	**Adverse events/AEs**
Tashkin et al. (1974) *Bronchial Asthma*	10 5 males 5 females Inclusion Criteria: -diagnosis of bronchial asthma -asthma relieved by bronchodilator medication -clinically stable Previous Marijuana Experience: -7 subjects had previous exposure to marijuana -amount of exposure <1 cigarette/month Exclusion Criteria: -no marijuana use ≤7 days of study -psychiatric illness	NIMH (NIDA) marijuana, smoked 0%, 2% THC Dronabinol, oral 0, 15mg Dosing is 7mg/kg of body weight of plant material Smoking Procedure: smoking of marijuana cigarette with each puff consisting of: 1) 2-4s deep inhale smoke, 2) 15s hold smoke in lungs 3) 5s exhale and breath normally 4) repeat till entire cigarette is smoked QD	Crossover *4, 1-day sessions, with at least 48 hours between sessions*	No primary outcome measure is specified Related outcome measure was sGaw	-Marijuana significantly increased sGaw (33-48%) compared to placebo and baseline	-Marijuana initially significantly increased pulse rate compared to placebo, and then at 90 minutes pulse rate was significantly decreased compared to baseline. -All subjects felt intoxicated after marijuana.

AE=Adverse Event; NIDA=National Institute of Drug Abuse; QD=drug administered one time per day; sGaw=Specific Airway Conductance; THC=delta-9-tetrahydrocannbinol

U.S. Department of Justice—Drug Enforcement Administration

Schedule of Controlled Substances: Maintaining Marijuana in Schedule I of the Controlled Substances Act

Background, Data, and Analysis: Eight Factors Determinative of Control and Findings Pursuant to 21 U.S.C. 812(b)

Prepared by: Office of Diversion Control, Drug and Chemical Evaluation Section, Washington, DC 20537

July 2016

Background

On December 17, 2009, Bryan Krumm, CNP, submitted a petition to the Drug Enforcement Administration (DEA) to initiate proceedings for a repeal of the rules or regulations that place marijuana[38] in schedule I of the Controlled Substances Act (CSA). The petition requests that marijuana be rescheduled in any schedule other than schedule I of the CSA. The petitioner claims that:

1. Marijuana has accepted medical use in the United States;
2. Studies have shown that smoked marijuana has proven safety and efficacy;
3. Marijuana is safe for use under medical supervision; and
4. Marijuana does not have the abuse potential for placement in schedule I

The DEA accepted this petition for filing on April 3, 2010.

The Attorney General may by rule transfer a drug or other substance between schedules of the CSA if she finds that such drug or other substance has a potential for abuse, and makes the findings prescribed by 21 U.S.C. 812(b) for the schedule in which such drug is to be placed. 21 U.S.C. 811(a)(1). The Attorney General has delegated this responsibility to the Acting Administrator of the DEA. 28 CFR 0.100(b).

In accordance with 21 U.S.C. 811(b), after gathering the necessary data, the DEA submitted the petition and necessary data to the Department of Health and Human Services (HHS) on May 6, 2011, and requested that HHS provide a scientific and medical evaluation and scheduling recommendation for marijuana. In documents dated June 3 and June 25, 2015, the acting Assistant Secretary for Health of the HHS[39] recommended to the DEA that marijuana continue to be controlled in Schedule I of the CSA, and provided to the DEA its scientific and medical evaluation titled "Basis for the Recommendation for Maintaining Marijuana in Schedule I of the Controlled Substances Act." The HHS's recommendations are binding on the DEA as to scientific and medical matters. 21 U.S.C. 811(b).

Before initiating proceedings to reschedule a substance, the CSA requires the Acting Administrator to determine whether the HHS scheduling recommendation, scientific and medical evaluation, and "all other relevant data" constitute substantial evidence that the drug should be rescheduled as proposed. 21 U.S.C. 811(b). The Acting Administrator must determine whether there is substantial evidence to conclude that the drug meets the criteria for placement in another schedule based on the criteria set forth in 21 U.S.C. 812(b). The CSA requires that both the DEA and the HHS consider the eight factors specified by Congress in 21 U.S.C. 811(c). This document lays out those considerations and is organized according to the eight factors. As DEA sets forth in detail below, the evidence shows:

1. *Actual or relative potential for abuse.* Marijuana has a high potential for abuse. Preclinical and clinical data show that it has reinforcing effects characteristic of drugs of abuse. National databases on actual abuse show marijuana is the most widely abused drug, including significant numbers of substance abuse treatment admissions. Data on marijuana seizures show widespread availability and trafficking.

2. *Scientific evidence of its pharmacological effect.* The scientific understanding of marijuana, cannabinoid receptors, and the endocannabinoid system continues to be studied and elucidated. Marijuana produces various pharmacological effects, including subjective (*e.g.,* euphoria, dizziness, disinhibition), cardiovascular, acute and chronic respiratory, immune system, and prenatal exposure effects, as well as behavioral and cognitive impairment.

3. *Current scientific knowledge.* There is no currently accepted medical use for marijuana in the United States. Marijuana sources are derived from numerous cultivated strains and may have different levels of Δ^9-THC and other cannabinoids. Under the five-element test for currently accepted medical use discussed in more detail below and upheld by the Court of Appeals for the District of Columbia in *Alliance for Cannabis Therapeutics* v. *DEA,* 15 F.3d 1131, 1135 (D.C. Cir. 1994) (hereinafter "*ACT*"), there is no complete scientific analysis of marijuana's chemical components; there are not adequate safety studies; there are not adequate and well-controlled efficacy studies; there is not a consensus of medical opinion concerning medical applications of marijuana; and the scientific evidence regarding marijuana's safety and efficacy is not widely available. To date, scientific and medical research has not progressed to the point that marijuana has a currently accepted medical use, even under conditions where its use is severely restricted.

4. *History and current pattern of abuse.* Marijuana continues to be the most widely used illicit drug. In 2014, there were 22.2 million current users. There were also 2.6 million new users, most of whom were less than 18 years of age. During the same period, marijuana was the most frequently identified drug exhibit in federal, state, and local forensic laboratories.

5. *Scope, duration, and significance of abuse.* Abuse of marijuana is widespread and significant. In 2014, for example, an estimated 6.5 million people aged 12 or older used marijuana on a daily or almost daily basis over a 12-month period. In addition, a significant proportion of all admissions for substance abuse treatment are for marijuana/hashish as their primary drug of abuse. In 2013, 16.8% of all such admissions—281,991 over the course of the year—were for primary marijuana/hashish abuse.

6. *Risk, if any, to public health.* Together with the health risks outlined in terms of pharmacological effects above, public health risks from acute use of marijuana include impaired psychomotor performance, impaired driving, and impaired performance on tests of learning and associative processes. Chronic use of marijuana

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[38] The Controlled Substances Act (CSA) defines marijuana as the following: "All parts of the plant *Cannabis sativa L.,* whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted there from), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination. 21 U.S.C. 802(16). Note that "marihuana" is the spelling originally used in the CSA. This document uses the spelling that is more common in current usage, "marijuana."

[39] As set forth in a memorandum of understanding entered into by the HHS, the Food and Drug Administration (FDA), and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of the NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations.

poses a number of other risks to the public health including physical as well as psychological dependence.

7. *Psychic or physiological dependence liability.* Long-term, heavy use of marijuana can lead to physical dependence and withdrawal following discontinuation, as well as psychic or psychological dependence. In addition, a significant proportion of all admissions for treatment for substance abuse are for primary marijuana abuse; in 2013, 16.8% of all admissions were for primary marijuana/hashish abuse, representing 281,991 individuals.

8. *Immediate precursor.* Marijuana is not an immediate precursor of any controlled substance.

As specified in 21 U.S.C. 812(b)(1), in order for a substance to be placed in schedule I, the Acting Administrator must find that:

A. The drug or other substance has a high potential for abuse.

B. The drug or other substance has no currently accepted medical use in treatment in the United States.

C. There is a lack of accepted safety for use of the drug or other substance under medical supervision.

To be classified in another schedule under the CSA (*e.g.,* II, III, IV, or V), a substance must have a "currently accepted medical use in treatment in the United States." 21 U.S.C. 812(b)(2)–(5). A substance also may be placed in schedule II if it is found to have "a currently accepted medical use with severe restrictions." 21 U.S.C. 812(b)(2). If a controlled substance has no such currently accepted medical use, it must be placed in schedule I. *See* Notice of Denial of Petition, 66 FR 20038 (Apr. 18, 2001) ("Congress established only one schedule—schedule I—for drugs of abuse with 'no currently accepted medical use in treatment in the United States' and 'lack of accepted safety for use . . . under medical supervision.' ").

A drug that is the subject of an approved new drug application (NDA) or abbreviated new drug application (ANDA) under Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), is considered to have a currently accepted medical use in treatment in the United States for purposes of the CSA. The HHS stated in its review, however, that FDA has not approved any NDA for marijuana for any indication.

In the absence of NDA or ANDA approval, DEA has established a five-element test for determining whether the drug has a currently accepted medical use in treatment in the United States. Under this test, a drug will be considered to have a currently accepted medical use only if the following five elements are satisfied:

1. The drug's chemistry is known and reproducible;

2. There are adequate safety studies;

3. There are adequate and well-controlled studies proving efficacy;

4. The drug is accepted by qualified experts; and

5. The scientific evidence is widely available.

57 FR 10499, 10506 (March 26, 1992). *See also ACT,* 15 F.3d at 1135.

As discussed in Factor 3, below, HHS concluded, and DEA agrees, that the scientific evidence is insufficient to demonstrate that marijuana has a currently accepted medical use under the five-element test. The evidence was insufficient in this regard also when the DEA considered petitions to reschedule marijuana in 1992 (57 FR 10499),[40] in 2001 (66 FR 20038), and in 2011 (76 FR 40552).[41] Little has changed since 2011 with respect to the lack of clinical evidence necessary to establish that marijuana has a currently accepted medical use. No studies have scientifically assessed the efficacy and full safety profile of marijuana for any specific medical condition.

The limited existing clinical evidence is not adequate to warrant rescheduling of marijuana under the CSA. To the contrary, the data in this scheduling review document show that marijuana continues to meet the criteria for schedule I control under the CSA for the following reasons:

1. Marijuana has a high potential for abuse.

2. Marijuana has no currently accepted medical use in treatment in the United States.

3. Marijuana lacks accepted safety for use under medical supervision.

Factor 1: The Drug's Actual or Relative Potential for Abuse

Marijuana is the most commonly abused illegal drug in the United States. It is also the most commonly used illicit drug by high school students in the United States. Further, marijuana is the most frequently identified drug by state, local and federal forensic laboratories. Marijuana's main psychoactive ingredient, Δ^9-tetrahydrocannabinol (Δ^9-THC),[42] is an effective reinforcer in laboratory animals, including primates and rodents. These animal studies both predict and support the observations that marijuana produces reinforcing effects in humans. Such reinforcing effects can account for the repeated abuse of marijuana.

A. Indicators of Abuse Potential

The HHS has concluded in its document, "Basis for the Recommendation for Maintaining Marijuana in Schedule I of the Controlled Substances Act," that marijuana has a high potential for abuse. The finding of "abuse potential" is critical for control under the Controlled Substances Act (CSA). Although the term is not defined in the CSA, guidance in determining abuse potential is provided in the legislative history of the Act (Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91–1444, 91st Cong., Sess. 2 (1970), reprinted in 1970 U.S.C.C.A.N. 4566, 4603). Accordingly, the following items are indicators that a drug or other substance has potential for abuse:

- *There is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or of the community; or*
- *There is significant diversion of the drug or drugs containing such a substance from legitimate drug channels; or*
- *Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice; or*
- *The drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.*

Of course, evidence of actual abuse of a substance is indicative that a drug has a potential for abuse.

In its recommendation, the HHS analyzed and evaluated data on marijuana as applied to each of the above four criteria. The analysis presented in the recommendation (HHS, 2015) is discussed below:

1. There is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or of the community.

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[40] *See Alliance for Cannabis Therapeutics* v. *DEA,* 15 F.3d 1131 (D.C. Cir. 1994).

[41] *See Americans for Safe Access* v. *DEA,* 706 F.3d 438 (D.C. Cir. 2013)(rhg den. 2013).

[42] The terms Δ^9-THC and THC are used interchangeably thoughout this document.

The HHS stated that some individuals are taking marijuana in amounts sufficient to create a hazard to their health and to the safety of other individuals and the community. Data from national databases on actual abuse of marijuana support the idea that a large number of individuals use marijuana. In its recommendation (HHS, 2015), the HHS presented data from the National Survey on Drug and Health (NSDUH) of the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Monitoring the Future (MTF) survey of the National Institute on Drug Abuse (NIDA), and the DEA has since updated this information. The most recent data from SAMHSA's NSDUH in 2014 reported that marijuana was the most used illicit drug. Among Americans aged 12 years and older, an estimated 22.2 million Americans used marijuana within the past month according to the 2014 NSDUH. In 2004, an estimated 14.6 million individuals reported using marijuana within the month prior to the study. The estimated rates in 2014 thus reflect an increase of approximately 7.6 million individuals over a 10-year period. According to the 2013 NSDUH report, an estimated 19.8 million individuals reported using marijuana. Thus, over a period of one year (2013 NSDUH–2014 NSDUH), there was an estimated increase of 2.4 million individuals in the United States using marijuana.

The results from the 2015 Monitoring the Future survey of 8th, 10th, and 12th grade students indicate that marijuana was the most widely used illicit drug in these age groups. Current monthly use was 6.5% of 8th graders, 14.8% of 10th graders, and 21.3% of 12th graders. The Treatment Episode Data Set (TEDS) in 2013 reported that marijuana abuse was the primary factor in 16.8 percent of non-private substance-abuse treatment facility admissions. In 2011, SAMHSA's Drug Abuse Warning Network (DAWN) reported that marijuana was mentioned in 36.4% (455,668 out of approximately 1.25 million) of illicit drug-related Emergency Department (ED) visits.

Data on the extent and scope of marijuana abuse are presented under Factors 4 and 5 of this analysis. Discussion of the health effects of marijuana is presented under Factor 2, and the assessment of risk to the public health posed by acute and chronic marijuana abuse is presented under Factor 6 of this analysis.

2. There is significant diversion of the drug or drugs containing such a substance from legitimate drug channels.

In accordance with the CSA, the only lawful source of marijuana in the United States is that produced and distributed for research purposes under the oversight of NIDA and in conformity with United States obligations under the Single Convention on Narcotic Drugs.[43] The HHS stated that there is a lack of significant diversion from legitimate drug sources, but that this is likely due to high availability of marijuana from illicit sources. Marijuana is not an FDA-approved drug product. Neither a New Drug Application (NDA) nor a Biologics License Application (BLA) has been approved for marketing in the United States. However, the marijuana used for nonclinical and clinical research represents a very small amount of the total amount of marijuana available in the United States and therefore information about marijuana diversion from legitimate sources is limited or not available.

The DEA notes that the magnitude of the demand for illicit marijuana is evidenced by information from a number of databases presented under Factor 4. Briefly, marijuana is the most commonly used illegal drug in the United States. It is also the most commonly used illicit drug by American high schoolers. Marijuana is the most frequently identified drug in state, local, and federal forensic laboratories, with increasing amounts of both domestically grown and of illicitly smuggled marijuana.

Given that marijuana has long been the most widely trafficked and abused controlled substance in the United States, and that all aspects of such illicit activity are entirely outside of the closed system of distribution mandated by the CSA, it may well be the case that there is little thought given to diverting marijuana from the small supplies produced for legitimate research purposes. Thus, the lack of data indicating diversion of marijuana from legitimate channels to the illicit market is not indicative of a lack of potential for abuse of the drug.

3. Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice.

The HHS stated that the FDA has not evaluated or approved an NDA or BLA for marijuana for any therapeutic indication. Consistent with federal law, therefore, an individual legitimately can take marijuana based on medical advice from a practitioner only by participating in research that is being conducted under an Investigational New Drug (IND) application. The HHS noted that there are several states as well as the District of Columbia which have passed laws allowing for individuals to use marijuana for purported "medical" use under certain circumstances, but data are not available yet to determine the number of individuals using marijuana under these state laws. Nonetheless, according to 2014 NSDUH data, 22.2 million American adults currently use marijuana (SAMHSA, 2015a). Based on the large number of individuals who use marijuana and the lack of an FDA-approved drug product, the HHS concluded that the majority of individuals using marijuana do so on their own initiative rather than by following medical advice from a licensed practitioner.

4. The drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

Marijuana and its primary psychoactive ingredient, Δ^9-THC, are controlled substances in schedule I under the CSA.

The HHS stated that one approved, marketed drug product contains synthetic Δ^9-THC, also known as dronabinol, and another approved, marketed drug product contains a cannabinoid-like synthetic compound that is structurally related to Δ^9-THC, the main active component in marijuana. Both products are controlled under the CSA.

Marinol is a schedule III drug product containing synthetic Δ^9-THC (dronabinol) formulated in sesame oil in soft gelatin capsules. Marinol was approved by the FDA in 1985 for the treatment of nausea and vomiting associated with cancer chemotherapy in patients who did not respond to conventional anti-emetic treatments. In 1992, FDA approved Marinol for the treatment of anorexia associated with weight loss in patients with acquired immunodeficiency syndrome (AIDS). Marinol was originally placed into schedule II and later rescheduled to schedule III under the CSA due to the low reports of abuse relative to marijuana.

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[43] *See* 76 FR 51403, 51409–51410 (2011) (discussing cannabis controls required under the Single Convention).

Cesamet is a drug product containing the schedule II substance nabilone, a synthetic substance structurally related to Δ9-THC. Cesamet was approved for marketing by the FDA in 1985 for the treatment of nausea and vomiting associated with cancer chemotherapy. All other naturally occurring cannabinoids in marijuana and their synthetic equivalents with similar chemical structure and pharmacological activity are already included as schedule I drugs under the CSA.

B. Abuse Liability Studies

In addition to the indicators suggested by the CSA's legislative history, data as to preclinical and clinical abuse liability studies, as well as actual abuse, including clandestine manufacture, trafficking, and diversion from legitimate sources, are considered in this factor.

Abuse liability evaluations are obtained from studies in the scientific and medical literature. There are many preclinical measures of a drug's effects that when taken together provide an accurate prediction of the human abuse liability. Clinical studies of the subjective and reinforcing effects in humans and epidemiological studies provide quantitative data on abuse liability in humans and some indication of actual abuse trends. Both preclinical and clinical studies have clearly demonstrated that marijuana and Δ9-THC possess the attributes associated with drugs of abuse: They function as a positive reinforcer to maintain drug-seeking behavior, they function as a discriminative stimulus, and they have dependence potential.

Preclinical and most clinical abuse liability studies have been conducted with the psychoactive constituents of marijuana, primarily Δ9-THC and its metabolite, 11-hydroxy-Δ9-THC. Δ9-THC's subjective effects are considered to be the basis for marijuana's abuse liability. The following studies provide a summary of that data.

1. Preclinical Studies

Δ9-THC, the primary psychoactive component in marijuana, is an effective reinforcer in laboratory animals, including primates and rodents, as these animals will self-administer Δ9-THC. These animal studies both predict and support the observations that Δ9-THC, whether smoked as marijuana or administered by other routes, produces reinforcing effects in humans. Such reinforcing effects can account for the repeated abuse of marijuana.

a. Drug Discrimination Studies

The drug discrimination paradigm is used as an animal model of human subjective effects (Solinas et al., 2006) and is a method where animals are able to indicate whether a test drug is able to produce physical or psychological changes similar to a known drug of abuse. Animals are trained to press one bar (in an operant chamber) when they receive a known drug of abuse and another bar when they receive a placebo. When a trained animal receives a test drug, if the drug is similar to the known drug of abuse, it will press the bar associated with the drug.

Discriminative stimulus effects of Δ9-THC have specificity for the pharmacological effects of cannabinoids found in marijuana (Balster and Prescott, 1992; Browne and Weissman, 1981; Wiley et al., 1993; Wiley et al., 1995). As mentioned by the HHS, the discriminative stimulus effects of cannabinoids appear to be unique because abused drugs of other classes including stimulants, hallucinogens, opioids, benzodiazepines, barbiturates, NMDA antagonists, and antipsychotics do not fully substitute for Δ9-THC.

Laboratory animals including monkeys (McMahon et al., 2009), mice (McMahon et al., 2008), and rats (Gold et al., 1992) are able to discriminate cannabinoids from other drugs and placebo. The major active metabolite of Δ9-THC, 11-hydroxy-Δ9-THC, generalizes to Δ9-THC (Browne and Weissman, 1981). In addition, according to the HHS, twenty-two other cannabinoids found in marijuana also substitute for Δ9-THC. At least one cannabinoid, CBD, does not substitute for Δ9-THC in rats (Vann et al., 2008).

b. Self-Administration Studies

Animal self-administration behavior associated with a drug is a commonly used method for evaluating if the drug produces rewarding effects and for predicting abuse potential (Balster, 1991; Balster and Bigelow, 2003). Drugs that are self-administered by animals are likely to produce rewarding effects in humans. As mentioned in the HHS review document, earlier attempts to demonstrate self-administration of Δ9-THC were unsuccessful and confounded by diet restrictions, animal restraint, and known analgesic activity of Δ9-THC at testing doses (Tanda and Goldberg, 2003; Justinova et al., 2003). Self-administration of Δ9-THC was first demonstrated by Tanda et al. (2000). Tanda et al. (2000) showed that squirrel monkeys that were initially trained to self-administer cocaine (30 μg/kg, i.v.) self-administered 2 μg/kg Δ9-THC (i.v.) and at a rate of 30 injections per one hour session. Tanda et al. (2000) used a lower dose of Δ9-THC that was rapidly delivered (0.2 ml injection over 200 ms) than in previous self-administration studies such that analgesic activity of Δ9-THC was not a confounding factor. The authors also stated that the doses were comparable to those doses used by humans who smoke marijuana. A CB1 receptor antagonist (SR141716) blocked this rewarding effect of THC.

Justinova et al. (2003) were able to demonstrate self-administration of Δ9-THC in drug-naïve squirrel monkeys (no previous exposure to other drugs). The authors tested the monkeys with several doses of Δ9-THC (1, 2, 4, 8, and 16 μg/kg, i.v.) and found that the maximal rates of self-administration were observed with the 4 μg/kg/infusion. Subsequently, Braida et al. (2004) reported that rats will self-administer Δ9-THC when delivered intracerebroventricularly (i.c.v.), but only at the lowest doses tested (0.01–0.02 μg/infusion, i.c.v.).

Self-administration behavior with Δ9-THC was found to be antagonized in rats and squirrel monkeys by rimonabant (SR141716A, CB1 antagonist) and the opioid antagonists (naloxone and naltrexone) (Tanda et al., 2000; Braida et al., 2004; Justinova et al., 2004).

c. Conditioned Place Preference Studies

Conditioned place preference (CPP) is a behavioral assay where animals are given the opportunity to spend time in two distinct environments: one where they previously received a drug and one where they received a placebo. If the drug is reinforcing, animals in a drug-free state will choose to spend more time in the environment paired with the drug when both environments are presented simultaneously.

CPP has been demonstrated with Δ9-THC in rats but only at low doses (0.075–1.0 mg/kg, i.p.; Braida et al., 2004). Rimonabant (0.25–1.0 mg/kg, i.p.) and naloxone (0.5–2.0 mg/kg, i.p.) antagonized Δ9-THC-mediated CPP (Braida et al., 2004). However, in another study with rats, rimonabant was demonstrated to induce CPP at doses ranging from 0.25–3.0 mg/kg (Cheer et al., 2000). Mice without μ-opioid receptors did not exhibit CPP to Δ9-THC (paired with 1 mg/kg Δ9-THC, i.p.) (Ghozland et al., 2002).

2. Clinical Studies

In its scientific review (HHS, 2015), the HHS provided a list of common subjective psychoactive responses to cannabinoids based on information from several references (Adams and Martin, 1996; Gonzalez, 2007; Hollister, 1986;

Hollister, 1988; Institute of Medicine, 1982). Furthermore, Maldonado (2002) characterized these subjective responses as pleasurable to most humans and are generally associated with drug-seeking and/or drug-taking. Later studies (Scherrer et al., 2009; Zeiger et al., 2010) reported that high levels of positive psychoactive effects correlate with increased marijuana use, abuse, and dependence. The list of the common subjective psychoactive effects provided by the HHS (HHS, 2015) is presented below:

(1) Disinhibition, relaxation, increased sociability, and talkativeness.

(2) Increased merriment and appetite, and even exhilaration at high doses.

(3) Enhanced sensory perception, which can generate an increased appreciation of music, art, and touch.

(4) Heightened imagination, which can lead to a subjective sense of increased creativity.

(5) Initial dizziness, nausea, tachycardia, facial flushing, dry mouth, and tremor.

(6) Disorganized thinking, inability to converse logically, time distortions, and short-term memory impairment.

(7) Ataxia and impaired judgment, which can impede driving ability or lead to an increase in risk-taking behavior.

(8) Illusions, delusions, and hallucinations that intensify with higher doses.

(9) Emotional lability, incongruity of affect, dysphoria, agitation, paranoia, confusion, drowsiness, and panic attacks, which are more common in inexperienced or high-dosed users.

The HHS mentioned that marijuana users prefer higher concentrations of the principal psychoactive component (Δ^9-THC) over lower concentrations. In a clinical study with marijuana users (n = 12, usage ranged from once a month to 4 times a week), subjects were given a choice of 1.95% Δ^9-THC marijuana or 0.63% Δ^9-THC marijuana after sampling both marijuana cigarettes in two choice sessions. The marijuana cigarette with high THC was chosen in 21 out of 24 choice sessions or 87.5% of the time (Chait and Burke, 1994). Furthermore, in a double-blind study, frequent marijuana users (n = 11, usage at least 2 times per month with at least 100 occasions) when given a low-dose of oral Δ^9-THC (7.5 mg) were able to distinguish the psychoactive effects better than occasional users (n = 10, no use within the past 4 years with 10 or fewer lifetime uses) and also experienced fewer sedative effects (Kirk and de Wit, 1999).

Marijuana has also been recognized by scientific experts to have withdrawal symptoms (negative reinforcement) following moderate and heavy use. As discussed further in Factor 7, the DEA notes that the American Psychiatric Association's (APA) Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM–5) included a list of withdrawal symptoms following marijuana [cannabis] use (DSM–5, 2013).

C. Actual Abuse of Marijuana—National Databases Related to Marijuana Abuse and Trafficking

Marijuana continues to be the most widely used illicit drug. Evidence of actual abuse can be defined by episodes/mentions in databases indicative of abuse/dependence. The HHS provided in its recommendation (HHS, 2015) information relevant to actual abuse of marijuana including data results from the National Survey on Drug Use and Health (NSDUH), a Monitoring the Future (MTF) survey, the Drug Abuse Warning Network (DAWN), and the Treatment Episode Data Set (TEDS). These data sources provide quantitative information on many factors related to abuse of a particular substance, including incidence and patterns of use, and profile of the abuser of specific substances. The DEA is providing updated information from these databases in this discussion. The DEA also includes data on trafficking and illicit availability of marijuana from DEA databases including the National Forensic Laboratory Information System (NFLIS) and the National Seizure System (NSS), formerly the Federal-wide Drug Seizure System (FDSS), as well as other sources of data specific to marijuana, including the Potency Monitoring Project and the Domestic Cannabis Eradication and Suppression Program (DCE/SP).

1. National Survey on Drug Use and Health (NSDUH)

The National Survey on Drug Use and Health (NSDUH) is conducted annually by the Department of Health and Human Service's Substance Abuse and Mental Health Services Administration (SAMHSA). SAMHSA is the primary source of estimates of the prevalence and incidence of pharmaceutical drugs, illicit drugs, alcohol, and tobacco use in the United States. The survey is based on a nationally representative sample of the civilian, non-institutionalized population 12 years of age and older. The survey excludes homeless people who do not use shelters, active military personnel, and residents of institutional group quarters such as jails and hospitals.

According to the 2014 NSDUH report, marijuana was the most commonly used and abused illicit drug. That data showed that there were 22.2 million people who were past month users (8.4%) among those aged 12 and older in the United States. (Note: NSDUH figures on marijuana use include hashish use; the relative proportion of hashish use to marijuana use is very low). Marijuana had the highest rate of past-year dependence or abuse in 2014. The NSDUH report estimates that 3.0 million people aged 12 or older used an illicit drug for the first time in 2014; a majority (70.3%) of these past year initiates reported that their first drug used was marijuana. Among those who began using illicit drugs in the past year, 65.6%, 70.3%, and 67.6% reported marijuana as the first illicit drug initiated in 2012, 2013, and 2014 respectively. In 2014, the average age of marijuana initiates among 12- to 49-year-olds was 18.5 years. These usage rates and demographics are relevant in light of the risks presented.

Marijuana had the highest rate of past year dependence or abuse of any illicit drug in 2014. The 2014 NSDUH report stated that 4.2 million persons were classified with substance dependence or abuse of marijuana in the past year (representing 1.6% of the total population aged 12 or older, and 59.0% of those classified with illicit drug dependence or abuse) based on criteria specified in the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM–IV).

Among past year marijuana users age 12 or older, 18.5% used marijuana on 300 or more days within the previous 12 months in 2014. This translates into 6.5 million people using marijuana on a daily or almost daily basis over a 12-month period, significantly more than the estimated 5.7 million daily or almost daily users in just the year before. Among past month marijuana users, 41.6% (9.2 million) used the drug on 20 or more days in the past month, a significant increase from the 8.1 million who used marijuana 20 days or more in 2013.

2. Monitoring the Future (MTF)

Monitoring the Future (MTF) is an ongoing study which is funded under a series of investigator-initiated competing research grants from the National Institute on Drug Abuse (NIDA). MTF tracks drug use trends among American adolescents in the 8th, 10th, and 12th grades. According to its 2015 survey results, marijuana was the most commonly used illicit drug, as was the case in previous years. Approximately 6.5% of 8th graders, 14.8% of 10th graders, and 21.3% of 12th graders surveyed in 2015 reported marijuana use during the past month prior to the survey. A number of high school students in 2015 also reported daily use in the past month, including 1.1%, 3.0%, and 6.0% of 8th, 10th, and 12th graders, respectively.

3. Drug Abuse Warning Network (DAWN), Emergency Department (ED) Visits

The Drug Abuse Warning Network (DAWN) is a public health surveillance system that monitors drug-related hospital emergency department (ED) visits to track the impact of drug use, misuse, and abuse in the United States. For the purposes of DAWN, the term "drug abuse" applies if the following conditions are met: (1) The case involved at least one of the following: use of an illegal drug, use of a legal drug contrary to directions, or inhalation of a non-pharmaceutical substance; and (2) the substance was used for one of the following reasons: because of drug dependence, to commit suicide (or attempt to commit suicide), for recreational purposes, or to achieve other psychic effects. Importantly, many factors can influence the estimates of ED visits, including trends in overall use of a substance as well as trends in the reasons for ED usage. For instance, some drug users may visit EDs for life-threatening issues while others may visit to seek care for detoxification because they needed certification before entering treatment. Additionally, DAWN data do not distinguish the drug responsible for the ED visit from other drugs that may have been used concomitantly. As stated in a DAWN report, "Since marijuana/hashish is frequently present in combination with other drugs, the reason for the ED visit may be more relevant to the other drug(s) involved in the episode."

In 2011, marijuana was involved in 455,668 ED visits out of 2,462,948 total ED visits involving all abuse or misuse in the United States and out of 1.25 million visits involving abuse or misuse of illicit drugs (excluding alcohol-related visits), as estimated by DAWN. This is lower than the number of ED visits involving cocaine (505,224) and higher than the number of ED visits involving heroin (258,482) and stimulants (*e.g.*, amphetamine, methamphetamine) (159,840). Visits involving the other major illicit drugs, such as MDMA, GHB, LSD and other hallucinogens, PCP, and inhalants, were much less frequent, comparatively.

In young patients, marijuana is the illicit drug most frequently involved in ED visits, according to DAWN estimates, with 240.2 marijuana-related ED visits per 100,000 population ages 12 to 17, 443.8 per 100,000 population ages 18 to 20, and 446.9 per 100,000 population ages 21 to 24.

4. Treatment Episode Data Set (TEDS) System

The Treatment Episode Data Set (TEDS) system is part of the SAMHSA Drug and Alcohol Services Information System and is a national census of annual admissions to state licensed or certified, or administratively tracked, substance abuse treatment facilities. The TEDS system contains information on patient demographics and substance abuse problems of admissions to treatment for abuse of alcohol and/or drugs in facilities that report to state administrative data systems. For this database, the primary substance of abuse is defined as the main substance of abuse reported at the time of admission. TEDS also allows for the recording of two other substances of abuse (secondary and tertiary).

In 2011, the TEDS system included 1,928,792 admissions to substance abuse treatment; in 2012 there were 1,801,385 admissions; and in 2013 there were 1,683,451 admissions. Marijuana/hashish was the primary substance of abuse for 18.3% (352,397) of admissions in 2011; 17.5% (315,200) in 2012; and 16.8% (281,991) in 2013. Of the 281,991 admissions for marijuana/hashish treatment in 2013, 24.3% used marijuana/hashish daily. Among those treated for marijuana/hashish as the primary substance in 2013, 27.4% were ages 12 to 17 years and 29.7% were ages 18 to 24 years. Those admitted for marijuana/hashish were mostly male (72.6%) and non-Hispanic (82.2%). Non-hispanic whites (43.2%) represented the largest ethnic group of marijuana admissions.

5. Forensic Laboratory Data

Data on marijuana seizures from federal, state, and local forensic laboratories have indicated that there is significant trafficking of marijuana. The National Forensic Laboratory System (NFLIS) is a program sponsored by the Drug Enforcement Administration's Office of Diversion Control. NFLIS systematically collects drug identification results and associated information from drug exhibits encountered by law enforcement and analyzed in federal, state, and local forensic laboratories. NFLIS is a comprehensive information system that includes data from 278 individual forensic laboratories that report more than 91% of the drug caseload in the U.S. NFLIS captures data for all drugs and chemicals identified and reported by forensic laboratories. More than 1,700 unique substances are represented in the NFLIS database.

Data from NFLIS showed that marijuana was the most frequently identified drug in federal, state, and local laboratories from January 2004 through December 2014. Marijuana accounted for between 29.47% and 34.84% of all drug exhibits analyzed annually during that time frame (Table 1).

Table 1. NFLIS Federal, State and Local Forensic Laboratory Data of Marijuana Reports (other than hashish)

Year	Reports	Percent of Total Reports
2004	454,582	34.42%
2005	483,134	32.53%
2006	520,060	32.55%
2007	525,668	33.66%
2008	526,420	34.07%
2009	536,888	34.30%
2010	544,418	34.91%
2011	495,937	33.42%
2012	485,591	32.02%
2013	452,839	30.70%
2014	432,989	29.27%
2015*	341,162	26.73%

NFLIS database queried 03-23-2016, by date of submission, all drugs reported

*2015 data are still being reported to NFLIS due to normal lag time.

Since 2004, the total number of reports of marijuana and the amount of marijuana encountered federally has remained high (see data from Federal-wide Drug Seizure System and Domestic Cannabis Eradication and Suppression Program below).

6. Federal-Wide Drug Seizure System

The Federal-wide Drug Seizure System (FDSS) contains information about drug seizures made within the jurisdiction of the United States by the Drug Enforcement Administration, the Federal Bureau of Investigation, United States Customs and Border Protection, and United States Immigration and Customs Enforcement. It also records maritime seizures made by the United States Coast Guard. Drug seizures made by other Federal agencies are included in the FDSS database when drug evidence custody is transferred to one of the agencies identified above. FDSS is now incorporated into the National Seizure System (NSS), which is a repository for information on clandestine laboratory and contraband (chemicals and precursors, currency, drugs, equipment and weapons). FDSS reports total federal drug seizures [in kilograms (kg)] of substances such as cocaine, heroin, MDMA, methamphetamine, and cannabis (marijuana and hashish). The yearly volume of cannabis seized (Table 2), consistently exceeding a thousand metric tons per year, shows that cannabis is very widely trafficked in the United States.

Table 2. Total Federal Seizures of Cannabis (Expressed in Kg)
(Source: NSS, U.S. Seizures, EPIC System Portal, queried 08-05-2015)

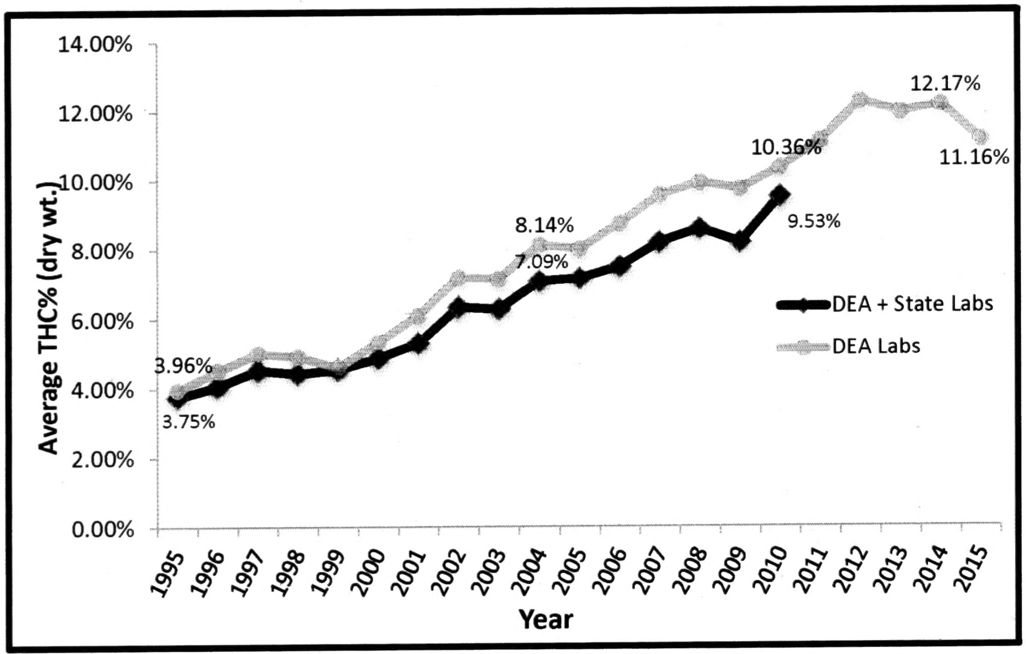
	2010	**2011**	**2012**	**2013**	**2014**
Cannabis	**4,071,328**	**3,622,256**	**2,756,439**	**2,622,494**	**1,768,277**
Marijuana	4,070,850	3,621,322	2,754,457	2,618,340	1,767,741
Hashish	478	934	1,982	4,154	536

7. Potency Monitoring Project

The University of Mississippi's Potency Monitoring Project (PMP), through a contract with the National Institute on Drug Abuse (NIDA), analyzes and compiles data on the Δ^9-THC concentrations of marijuana, hashish and hash oil samples provided by DEA regional laboratories and by state and local police agencies. After 2010, PMP has analyzed only marijuana samples provided by DEA regional laboratories. As indicated in Figure 1, the percentage of Δ^9-THC increased from 1995 to 2010 with an average THC content of 3.75% in 1995 and 9.53% in 2010. In examining marijuana samples only provided by DEA laboratories, the average Δ^9-THC content was 3.96% in 1995 in comparison to 11.16% in 2015.

Figure 1. Average Percentage of Δ^9-THC in Samples of Seized Marijuana (1995 – 2015)*

(Source: The University of Mississippi Potency Monitoring Program, Quarterly Report # 131)



*PMP discontinued analysis of state samples after 2010.

**Data for 2015 are incomplete. Figure 1 contains percentage of Δ^9-THC data through Dec. 22. Due to lack of funding, 4,177 samples haven't yet been analyzed.

8. The Domestic Cannabis Eradication and Suppression Program

The Domestic Cannabis Eradication and Suppression Program (DCE/SP) was established in 1979 to reduce the supply of domestically cultivated marijuana in the United States. The program was designed to serve as a partnership between federal, state, and local agencies. Only California and Hawaii were active participants in the program at its inception. However, by 1982 the program had expanded to 25 states and by 1985 all 50 states were participants. Cannabis is cultivated in remote locations and frequently on public lands and illicitly grown in all states. Data provided by the DCE/SP (Table 3) show that in the United States in 2014, there were 3,904,213 plants eradicated in outdoor cannabis cultivation areas compared to 2,597,798 plants in 2000. Significant quantities of marijuana were also eradicated from indoor cultivation operations. There were 396,620 indoor plants eradicated in 2014 compared to 217,105 eradicated in 2000.

Table 3. Domestic Cannabis Eradication, Outdoor and Indoor Plants Seized, 2000–2014 (Source: Domestic Cannabis Eradication/Suppression Program)

	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Outdoor	2,597,798	3,068,632	3,128,800	3,427,923	2,996,144	3,938,151	4,830,766	6,599,599	7,562,322	9,980,038	9,866,766	6,226,288	3,631,582	4,033,513	3,904,213
Indoor	217,105	236,128	213,040	223,183	203,896	270,935	400,892	434,728	450,986	414,604	462,419	509,231	302,377	361,727	396,620
Total	2,814,903	3,304,760	3,341,840	3,651,106	3,200,040	4,209,086	5,231,658	7,034,327	8,013,308	10,394,642	10,329,185	6,735,519	3,933,959	4,395,240	4,300,833

The recent statistics from these various surveys and databases show that marijuana continues to be the most commonly used illicit drug, with considerable rates of heavy abuse and dependence. They also show that marijuana is the most readily available illicit drug in the United States.

Petitioners' Major Comment in Relation to Factor 1 and the Government's Responses

(1) The petitioner states on pages 1–2 of the petition that *"[p]ure THC (Marinol), the primary psychoactive ingredient in marijuana has been placed in Schedule III. However, unlike Marinol, marijuana has other cannabinoids that help to mitigate the psychoactive effects of THC and reduce the potential for abuse. Therefore, the THC in marijuana can not have the high potential for abuse required for placement in Schedule I."*

First, the petitioners failed to review the indicators of abuse potential, as discussed in the legislative history of the CSA. The petitioners did not use data on marijuana usage, diversion, psychoactive properties, and dependence in their evaluation of marijuana abuse potential. The HHS and the DEA discuss those indicators above in this factor. HHS's evaluation of the full range of data led HHS and DEA to conclude that marijuana has a high potential for abuse.

Second, the HHS indicated that modulating effects of the other cannabinoids in marijuana on Δ^9-THC have not been demonstrated in controlled studies. Specifically, HHS concluded in its 8-factor analysis that "any possible mitigation of delta-9-THC's psychoactive effects by CBD will not occur for most marijuana users."

Marinol was rescheduled from schedule II to schedule III on July 2, 1999 (64 FR 35928, DEA 1999). In assessing Marinol, HHS compared Marinol to marijuana on several aspects of abuse potential and found that major differences between the two, such as formulation, availability, and usage, contribute to differences in abuse potential. The psychoactive effects from smoking are generally more rapid and intense that those that occur through oral administration (HHS, 2015; Wesson and Washburn, 1990; Hollister and Gillespie, 1973). Therefore, as concluded by both the HHS and the DEA, the delayed onset of action and longer duration of action from an oral dose of Marinol may contribute in limiting the abuse potential of Marinol relative to marijuana, which is most often smoked. The HHS also stated that the extraction and purification of dronabinol from the encapsulated sesame oil mixture of Marinol is highly complex and difficult and that the presence of sesame oil mixture may preclude the smoking of Marinol-laced cigarettes.

Additionally, the FDA approved a New Drug Application (NDA) for Marinol, indicating a legitimate medical use for Marinol in the United States and allowing for Marinol to be rescheduled into schedule II and subsequently into schedule III of the CSA. The HHS mentioned that marijuana and Marinol differ on a wide variety of factors and these differences are major reasons for differential scheduling of marijuana and Marinol. Marijuana, as discussed more fully in Factors 3 and 6, does not have a currently accepted medical use in the United States, is highly abused, and has a lack of accepted safety.

Finally, the DEA notes that under the CSA, for a substance to be placed in schedule II, III, IV, or V, it must have a currently accepted medical use in treatment in the United States.[44] As DEA has previously stated, Congress established only one schedule, schedule I, for drugs of abuse with "no currently accepted medical use in treatment in the United States." 76 FR 40552 (2011). Thus, any attempt to compare the relative abuse potential of schedule I substance to that of a substance in another schedule is inconsequential since a schedule I substance must remain in schedule I until it has been found to have a currently accepted medical use in treatment in the United States.

Factor 2: Scientific Evidence of the Drug's Pharmacological Effects, if Known

The HHS stated that there are large amounts of scientific data on the neurochemistry, mechanistic effects, toxicology, and pharmacology of marijuana. A scientific evaluation, as conducted by the HHS and the DEA, of marijuana's neurochemistry, human and animal behavioral pharmacology, central nervous system effects, and other pharmacological effects (*e.g.* cardiovascular, immunological effects) is presented below.

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[44] *See* Americans for Safe Access, 706 F.3d at 440.

Neurochemistry

Marijuana contains numerous constituents such as cannabinoids that have a variety of pharmacological actions. The HHS stated that different marijuana samples derived from various cultivated strains may differ in their chemical constituents including Δ^9-THC and other cannabinoids. Therefore marijuana products from different strains will have different biological and pharmacological effects. The chemical constituents of marijuana are discussed further in Factor 3.

The primary site of action for cannabinoids such as Δ^9-THC is at the cannabinoid receptor. Two cannabinoid receptors, CB1 and CB2, have been identified and characterized (Battista et al., 2012; Piomelli, 2005) and are G-protein-coupled receptors. Activation of these inhibitory G-protein-coupled receptors inhibits adenylate cyclase activity, which prevents conversion of ATP to cyclic AMP. Cannabinoid receptor activation also results in inhibition of N- and P/Q-type calcium channels and activates inwardly rectifying potassium channels (Mackie et al., 1995; Twitchell et al., 1997). The HHS mentioned that inhibition of N-type calcium channels decreases neurotransmitter release and this may be the underlying mechanism in the ability of cannabinoids to inhibit acetylcholine, norepinephrine and glutamate from specific areas of the brain. These cellular actions may underlie the antinociceptive and psychoactive effects of cannabinoids. Δ^9-THC acts as an agonist at cannabinoid receptors.

CB1 receptors are primarily found in the central nervous system and are located mainly in the basal ganglia, hippocampus and cerebellum of the brain (Howlett et al., 2004). CB1 receptors are also located in peripheral tissues such as the immune system (De Petrocellis and Di Marzo, 2009), but the concentration of CB1 receptors there is considerably lower than in the central nervous system (Herkenham et al., 1990; 1992). CB2 receptors are found primarily in the immune system and predominantly in B lymphocytes and natural killer cells (Bouaboula et al., 1993). CB2 receptors are also found in the central nervous system, primarily in the cerebellum and hippocampus (Gong et al., 2006).

Two endogenous ligands to the cannabinoid receptors, anandamide and arachidonyl glycerol (2–AG), were identified in 1992 (Devane et al., 1992) and 1995 (Mechoulam et al., 1995), respectively. Anandamide is a low-efficacy agonist (Brievogel and Childers, 2000) and 2–AG is a high efficacy agonist (Gonsiorek et al., 2000) to the cannabinoid receptors. These endogenous ligands are present in both the central nervous system and in the periphery (HHS, 2015).

Δ^9-THC and cannabidiol (CBD) are two of the major cannabinoids in marijuana. Δ^9-THC is the major psychoactive cannabinoid (Wachtel et al., 2002). Δ^9-THC has similar affinity for CB1 and CB2 receptors and acts as a weak agonist at CB2 receptors. The HHS indicated that activation of CB1 receptors mediates psychotropic effects of cannabinoids. CBD has low affinity for both CB1 and CB2 receptors. CBD has antagonistic effects at CB1 receptors, and some inverse agonistic properties at CB2 receptors.

Animal Behavioral Effects

Animal abuse potential studies (drug discrimination, self-administration, conditioned place preference) are discussed more fully in Factor 1. Briefly, it was consistently demonstrated that Δ^9-THC, the primary psychoactive component in marijuana, and other cannabinoids in marijuana have a distinct drug discriminative profile. In addition, animals self-administer Δ^9-THC, and Δ^9-THC in low doses produces conditioned place preference.

Central Nervous System Effects

Psychoactive Effects

The clinical psychoactive effects of marijuana are discussed more fully in Factor 1. Briefly, the psychoactive effects from marijuana use are considered pleasurable and associated with drug-seeking or drug-taking (HHS, 2015; Maldonado, 2002). Further, it was noted by HHS that marijuana users prefer higher concentrations of the principal psychoactive component (Δ^9-THC) over lower concentrations (HHS, 2015).

Studies have evaluated psychoactive effects of THC in the presence of high CBD, CBC, or CBN ratios. Even though some studies suggest that CBD may decrease some of Δ^9-THC's psychoactive effects, the HHS found that the ratios of CBD to Δ^9-THC administered in the studies were not comparable to the amounts found in marijuana used by most people (Dalton et al., 1976; Karniol et al., 1974; Zwardi et al., 1982). In fact, the CBD ratios in these studies are significantly higher than the CBD found in most marijuana currently found on the streets (Mehmedic et al., 2010). HHS indicated that most of the marijuana available on the street has a high THC and low CBD content and therefore any lessening of THC's psychoactive effects by CBD will not occur for most marijuana users (HHS, 2015). Dalton et al. (1976) reported that when volunteers smoked cigarettes with a ratio of 7 CBD to 1 Δ^9-THC (0.15 mg/kg CBD and 0.025 mg/kg Δ^9-THC), there was a significant decrease in ratings of acute subjective effects and achieving a "high" in comparison to smoking Δ^9-THC alone. In oral administration studies, the subjective effects and anxiety produced by combination of CBD and THC in a ratio of at least 1:2 CBD to Δ^9-THC (15, 30, 60 mg CBD to 30 mg Δ^9-THC; Karniol et al., 1974) or a ratio of 2:1 CBD to Δ^9-THC (1 mg/kg CBD to 0.5 mg/kg Δ^9-THC; Zuardi et al., 1982) are less than those produced by Δ^9-THC administered alone.

In one study (Ilan et al., 2005), the authors calculated the naturally occurring concentrations of CBC and CBD in marijuana cigarettes with either 1.8 or 3.6% Δ^9-THC by weight. The authors varied the concentrations of CBC and CBD for each concentration of Δ^9-THC in the marijuana cigarettes. Administrations in healthy marijuana users (n=23) consisted of either: (1) Low CBC (0.1% by weight) and low CBD (0.2% by weight); (2) high CBC (0.5% by weight) and low CBD; (3) low CBC and high CBD (1.0% by weight); or 4) high CBC and high CBD and the users were divided into low Δ^9-THC (1.8% by weight) and high Δ^9-THC (3.6% by weight) groups. Subjective psychoactive effects were significantly greater for all groups in comparison to placebo and there were no significant differences in effects among the treatments (Ilan et al., 2005).

The HHS also referred to a study with Δ^9-THC and cannabinol (CBN) (Karniol et al., 1975). In this study, oral administration of either 12.5, 25, or 50 mg CBN combined with 25 mg Δ^9-THC (ratio of at least 1:2 CBN to Δ^9-THC) significantly increased subjective psychoactive ratings of Δ^9-THC compared to Δ^9-THC alone (Karniol et al., 1975).

Behavioral Impairment

Several factors may influence marijuana's behavioral effects including the duration (chronic or short term), frequency (daily, weekly, or occasionally), and amount of use (heavy or moderate). Researchers have examined how long behavioral impairments persist following chronic marijuana use. These studies used self-reported histories of exposure duration, frequency, and amount of marijuana use, and administered several performance and cognitive tests at different time points following marijuana abstinence. According to HHS, behavioral impairments may persist for up to 28 days of abstinence in chronic marijuana users.

Psychoactive effects of marijuana can lead to behavioral impairment including cognitive decrements and decreased ability to operate motor vehicles (HHS, 2015). Block et al. (1992) evaluated cognitive measures in 48 healthy male subjects following smoking a marijuana cigarette that contained 2.57% or 19 mg Δ^9-THC by weight or placebo. Each subject participated in eight sessions (four sessions with marijuana; four sessions with placebo) and several cognitive and psychomotor tests were administered (*e.g.* verbal recall, facial recognition, text learning, reaction time). Marijuana significantly impaired performances in most of these cognitive and psychomotor tests (Block et al., 1992).

Ramaekers et al. (2006) reported that in 20 recreational users of marijuana, acute administration of 250 μg/kg and 500 μg/kg Δ^9-THC in smoked marijuana resulted in dose-dependent impairments in cognition, motor impulsivity, motor control (tracking impairments), and risk taking. In another study (Kurzthaler et al., 1999), when 290 μg/kg Δ^9-THC was administered via a smoked marijuana cigarette in 30 healthy volunteers with no history of substance abuse there were significant impairments of motor speed and accuracy. Furthermore, administration of 3.95% Δ^9-THC in a smoked marijuana cigarette increased the latency in a task of simulated braking in a vehicle (Liguori et al., 1998). The HHS noted that the motor impairments reported in these studies (Kurzthaler et al., 1999; Liguori et al., 1998) are critical skills needed for operating a vehicle.

As mentioned in the HHS document, some studies examined the persistence of the behavioral impairments immediately after marijuana administration. Some of marijuana's acute effects may still be present for at least 24 hours after the acute psychoactive effects have subsided. In a brief communication, Heishmann et al. (1990) reported that there were cognitive impairments (digit recall and arithmetic tasks) in two out of three experienced marijuana smokers for 24 hours after smoking marijuana cigarettes containing 2.57% Δ^9-THC. However, Fant et al. (1998) evaluated subjective effects and performance measures for up to 25 hours in 10 healthy males after exposure to either 1.8% or 3.6% Δ^9-THC in marijuana cigarettes. Peak decrements in subjective and performance measures were noted within 2 hours of marijuana exposure but there were minimal residual alterations in subjective or performance measures at 23–25 hours after exposure.

Persistence of behavioral impairments following repeated and chronic use of marijuana has also been investigated and was reviewed in the HHS document (HHS, 2015). In particular, researchers examined how long behavioral impairments last following chronic marijuana use. In studies examining persistence of effects in chronic and heavy marijuana users, there were significant decrements in cognitive and motor function tasks in all studies of up to 27 days, and in most studies at 28 days (Solowij et al., 2002; Messinis et al., 2006; Lisdahl and Price, 2012; Pope et al., 2002; Bolla et al., 2002; Bolla et al., 2005). In studies that followed heavy marijuana users for longer than 28 days and up to 20 years of marijuana abstinence, cognitive and psychomotor impairments were no longer detected (Fried et al., 2005; Lyons et al., 2004; Tait et al., 2011). For example, Fried et al. (2005) reported that after 3 months of abstinence from marijuana, any deficits in intelligence (IQ), memory, and processing speeds following heavy marijuana use were no longer observed (Fried et al., 2005). In a meta-analysis that examined non-acute and long-lasting effects of marijuana, any deficits in neurocognitive performance that were observed within the first month were no longer apparent after approximately one month of abstinence (Schreiner and Dunn, 2012). HHS further notes that in moderate marijuana users deficits in decision-making skills were not observed after 25 days of abstinence and additionally IQ, immediate memory and delayed memory skills were not significantly impacted as observed with heavy and chronic marijuana users (Fried et al., 2005; HHS, 2015)

As mentioned in the HHS document (HHS, 2015), the intensity and persistence of neurological impairment from chronic marijuana use also may be dependent on the age of first use. In two separate smaller scale studies (less than 100 participants per exposure group), Fontes et al. (2011) and Gruber et al. (2012) compared neurological function in early onset (chronic marijuana use prior to age 15 or 16) and late onset (chronic marijuana use after age 15 or 16) heavy marijuana users and found that there were significant deficits in executive neurological function in early onset users which were not observed or were less apparent in late onset users. In a prospective longitudinal birth cohort study following 1,037 individuals (Meier et al., 2012), a significant decrease in IQ and neuropsychological performance was observed in adolescent-onset users and persisted even after abstinence from marijuana for at least one year. However, Meier et al (2012) reported in there was no significant change in IQ in adult-onset users.

The HHS noted that there is some evidence that the severity of the persistent neurological impairments may also be due in part to the amount of marijuana usage. In the study mentioned above, Gruber et al. (2012) found that the early onset users consumed three times as much marijuana per week and used it twice as often as late onset users. Meier et al. (2012) reported in their study, mentioned above, that there was a correlation between IQ deficits in adolescent onset users and the increased amount of marijuana used.

Behavioral Effects of Prenatal Exposure

In studies that examined effects of prenatal marijuana exposure, many of the pregnant women also used alcohol and tobacco in addition to marijuana. Even though other drugs were used in conjunction with marijuana, there is evidence of an association between heavy prenatal marijuana exposure and deficits in some cognitive function. There have been two prospective longitudinal birth cohort studies following individuals prenatally exposed to marijuana from birth until adulthood: The Ottawa Prenatal Prospective Study (OPPS; Fried et al., 1980), and the Maternal Health Practices and Child Development Project (MHPCD; Day et al., 1985). Both longitudinal studies report that heavy prenatal marijuana use is associated with decreased performance on tasks assessing memory, verbal and quantitative reasoning in 4-year-olds (Fried and Watkinson, 1990) and in 6 year olds (Goldschmidt et al., 2008). In subsequent studies with the OPPS cohort, deficits in sustained attention were reported in children ages 6 and 13–16 years (Fried et al., 1992; Fried, 2002) and deficits in executive neurological function were observed in 9- and 12-year-old children (Fried et al., 1998). DEA further notes that with the MHPCD cohort, follow-up studies reported an increased rate of delinquent behavior (Day et al., 2011) and decreased achievement test scores (Goldschmidt et al., 2012) at age 14. When the MHPCD cohort was followed to age 22, there was a marginal ($p =$ 0.06) increase in psychosis with prenatal marijuana exposure and early onset of marijuana use (Day et al., 2015).

Association of Marijuana Use With Psychosis

There has been extensive research to determine whether marijuana usage is associated with development of schizophrenia or other psychoses, and the HHS indicated that the available data do not suggest a causative link between marijuana and the development of psychosis (HHS, 2015; Minozzi et al., 2010). As mentioned in the HHS review (HHS, 2015), numerous large scale longitudinal studies demonstrated that subjects who used marijuana do not have a greater incidence of psychotic diagnoses compared to non-marijuana users (van Os et al., 2002; Fergusson et al., 2005; Kuepper et al., 2011). Further, the HHS commented that when analyzing the available data examining the association between marijuana and psychosis, it is critical to differentiate whether the patients in a study are already diagnosed with psychosis or if the individuals have a limited number of symptoms associated with psychosis without qualifying for a diagnosis of the disorder.

As mentioned by the HHS, some of the studies examining the association between marijuana and psychosis utilized non-standard methods to categorize psychosis and these methods did not conform to the criteria in the Diagnostic and Statistical Manual (DSM–5) or the International Classification of Diseases (ICD–10) and would not be appropriate for use in evaluating the association between marijuana use and psychosis. For example, researchers characterized psychosis as "schizophrenic cluster" (Maremmani et al., 2004), "subclinical psychotic symptoms" (van Gastel et al., 2012), "pre-psychotic clinical high risk" (van der Meer et al., 2012), and symptoms related to "psychosis vulnerability" (Griffith-Lendering et al., 2012).

The HHS discussed an early epidemiological study conducted by Andreasson et al. (1987), which examined the link between psychosis and marijuana use. In this study, about 45,000 18- and 19-year-old male Swedish subjects provided detailed information on their drug-taking history and 274 of these subjects were diagnosed with schizophrenia over a 14-year period (1969–1983). Out of the 274 subjects diagnosed with psychosis, 21 individuals (7.7%) had used marijuana more than 50 times, while 197 individuals (72%) never used marijuana. As presented by the authors (Andreasson et al., 1987), individuals who claimed to take marijuana on more than 50 occasions were 6 times more likely to be diagnosed with schizophrenia than those who had never consumed the drug. The authors concluded that marijuana users who are vulnerable to developing psychoses are at the greatest risk for schizophrenia. In a 35 year follow up to the subjects evaluated in Andreasson et al. (1987), Manrique-Garcia et al. (2012) reported similar findings. In the follow up study, 354 individuals developed schizophrenia. Of those, 32 individuals (9%) had used marijuana more than 50 times and were 6.3 times more likely to develop schizophrenia. 255 of the 354 individuals (72%) never used marijuana.

The HHS also noted that many studies support the assertion that psychosis from marijuana usage may manifest only in individuals already predisposed to development of psychotic disorders. Marijuana use may precede diagnosis of psychosis (Schimmelmann et al., 2011), but most reports indicate that prodromal symptoms of schizophrenia are observed prior to marijuana use (Schiffman et al., 2005). In a review examining gene-environmental interaction between marijuana exposure and the development of psychosis, it was concluded that there is some evidence to support that marijuana use may influence the development of psychosis but only for susceptible individuals (Pelayo-Teran et al., 2012).

Degenhardt et al. (2003) modeled the prevalence of schizophrenia against marijuana use across eight birth cohorts in individuals born during 1940 to 1979 in Australia. Even though there was an increase in marijuana use in the adult subjects over this time period, there was not an increase in diagnoses of psychosis for these same subjects. The authors concluded that use of marijuana may increase schizophrenia only in persons vulnerable to developing psychosis.

Cardiovascular and Autonomic Effects

The HHS stated that acute use of marijuana causes an increase in heart rate (tachycardia) and may increase blood pressure (Capriotti et al., 1988; Benowitz and Jones, 1975). There is some evidence that associates the increased heart rate from Δ^9-THC exposure with excitation of the sympathetic and depression of the parasympathetic nervous systems (Malinowska et al., 2012). Tolerance to tachycardia develops with chronic exposure to marijuana (Jones, 2002; Sidney, 2002).

Prolonged exposure to Δ^9-THC results in a decrease in heart rate (bradycardia) and hypotension (Benowitz and Jones, 1975). These effects are thought to be mediated through peripherally located, presynaptic CB1 receptor inhibition of norepinephrine release with possible direct activation of vascular cannabinoid receptors (Wagner et al., 1998; Pacher et al., 2006).

As stated in the HHS recommendation (HHS, 2015), marijuana exposure causes orthostatic hypotension (fainting-like feeling; sudden drop in blood pressure upon standing up) and tolerance can develop to this effect upon repeated, chronic exposure (Jones, 2002). Tolerance to orthostatic hypotension is potentially related to plasma volume expansion, but tolerance does not develop to supine hypotensive effects (Benowitz and Jones, 1975).

Marijuana smoking, particularly by those with some degree of coronary artery or cerebrovascular disease, poses risks such as increased cardiac work, increased catecholamines and carboxyhemoglobin, myocardial infarction and postural hypotension (Benowitz and Jones, 1981; Hollister, 1988; Mittleman et al., 2001; Malinowska et al., 2012). However, electrocardiographic changes were minimal after administration of large cumulative doses of Δ^9-THC (Benowitz and Jones, 1975)

The DEA notes two recent reports that reviewed several case studies on marijuana and cardiovascular complications (Panayiotides, 2015; Hackam, 2015). Panayiotides (2015) reported that approximately 25.6% of the cardiovascular cases from marijuana use resulted in death from data provided by the French Addictovigilance Network during the period of 2006–2010. Several case studies on marijuana usage and cardiovascular events were discussed and it was concluded that although a causal link cannot be established due to not knowing exact amounts of marijuana used in the cases and confounding variables, the available evidence supports a link between marijuana and cardiotoxicity. Hackham (2015) reviewed 34 case reports or case series reports of marijuana and stroke/ischemia in 64 stroke patients and reported that in 81% of the cases there was a temporal relationship between marijuana usage and stroke or ischemic event. The author concluded that collective analysis of the case reports supports a causal link between marijuana use and stroke.

Respiratory Effects

The HHS stated that transient bronchodilation is the most typical respiratory effect of acute exposure to marijuana (Gong et al., 1984). In a recent longitudinal study, information on marijuana use and pulmonary data function were collected from 5,115 individuals over 20 years from 4 communities in the United States (Oakland, CA; Chicago, IL; Minneapolis, MN; Birmingham, AL) (Pletcher et al., 2012). Of the 5,115 individuals, 795 individuals reported use of only marijuana (without tobacco). The authors reported that occasional use of marijuana (7 joint-years for lifetime or 1 joint/day for 7 years or 1 joint/week for 49 years) does not adversely affect pulmonary function. Pletcher et al. (2012) further concluded that there is some preliminary evidence suggesting that heavy marijuana use may have a detrimental effect on pulmonary function, but the sample size of heavy marijuana users in the study was too small. Further, as mentioned in the HHS recommendation document (HHS, 2015), long-term use of marijuana may lead to chronic cough, increased sputum, as well as increased frequency of chronic bronchitis and pharyngitis (Adams and Martin, 1996; Hollister, 1986).

The HHS stated that the evidence that marijuana may lead to cancer of the respiratory system is inconsistent, with some studies suggesting a positive correlation while others do not (Lee and Hancox, 2011; Tashkin, 2005). The HHS noted a case series that reported lung cancer occurrences in three marijuana smokers (age range 31–37 years) with no history of tobacco smoking (Fung et al., 1999). Furthermore, in a case-control study (n = 173 individuals with squamous cell carcinoma of the head and neck; n = 176 controls; Zhang et al., 1999), prevalence of marijuana use was 9.7% in controls and 13.9% in cases and the authors reported that marijuana use may dose-dependently interact with mutagenic sensitivity, cigarette smoking, and alcohol use to increase risk associated with head and neck cancers (Zhang et al., 1999). However, in a large clinical study with 1,650 subjects, no positive correlation was found between marijuana use and lung cancer (Tashkin et al., 2006). This finding held true regardless of the extent of marijuana use when both tobacco use and other potential confounding factors were controlled. The HHS concluded that new evidence suggests that the effects of smoking marijuana on respiratory function and cancer are different from the effects of smoking tobacco (Lee and Hancox, 2011).

The DEA further notes the publication of recent review articles critically evaluating the association between marijuana and lung cancer. Most of the reviews agree that the association is weak or inconsistent (Huang et al., 2015; Zhang et al., 2015; Gates et al., 2014; Hall and Degenhardt, 2014). Huang et al. (2015) identified and reviewed six studies evaluating the association between marijuana use and lung cancer and the authors concluded that an association is not supported most likely due to the small amounts of marijuana smoked in comparison to tobacco. Zhang et al. (2015) examined six case control studies from the US, UK, New Zealand, and Canada within the International Lung Cancer Consortium and found that there was a weak association between smoking marijuana and lung cancer in individuals who never smoked tobacco, but precision of the association was low at high marijuana exposure levels. Hall and Degenhardt (2014) noted that even though marijuana smoke contains several of the same carcinogens and co-carcinogens as tobacco smoke (Roth et al., 1998) and has been found to be mutagenic and carcinogenic in the mouse skin test, epidemiological studies have been inconsistent, but more consistent positive associations have been reported in case control studies. Finally Gates et al. (2014), reviewed the studies evaluating marijuana use and lung cancer and concluded that there is evidence that marijuana produces changes in the respiratory system (precursors to cancer) that could lead to lung cancer, but overall association is weak between marijuana use and lung cancer especially when controlling for tobacco use.

Endocrine System

Reproductive Hormones

The HHS stated that administration of marijuana to humans does not consistently alter the endocrine system. In a controlled human exposure study (n = 4 males), subjects were acutely administered smoked marijuana containing 2.8% Δ^9-THC or placebo and an immediate significant decrease in luteinizing hormone and an increase in cortisol was reported in the subjects that smoked marijuana (Cone et al., 1986). Furthermore, as cited by the HHS, two later studies (Dax et al., 1989; Block et al., 1991) reported no changes in hormone levels. Dax et al. (1989) recruited male volunteers (n = 17) that were occasional or heavy users of marijuana. Following exposure to smoked Δ^9-THC (18 mg/cigarette) or oral Δ^9-THC (10 mg three times per day for three days and on the morning of the fourth day), the subjects in that study showed no changes in plasma adrenocorticotropic hormone (ACTH), cortisol, prolactin, luteinizing hormone, or testosterone levels. Additionally, Block et al. (1991) compared plasma hormone levels amongst non-users as well as infrequent, moderate, and frequent users of marijuana (n = 93 men and 56 women) and found that chronic use of marijuana (infrequent, moderate, and frequent users) did not significantly alter concentrations of testosterone, luteinizing hormone, follicle stimulating hormone, prolactin, or cortisol.

The HHS noted that there is a discrepancy in the effect of marijuana on female reproductive system functionality between animals and humans (HHS, 2015). Female rhesus monkeys that were administered 2.5 mg/kg Δ^9-THC, i.m., during days 1–18 of the menstrual cycle had reduced progesterone levels and ovulation was suppressed (Asch et al., 1981). However, women who smoked marijuana (1 gram marijuana cigarette with 1.8% Δ^9-THC) during the periovulatory period (24–36 hours prior to ovulation) did not exhibit changes in reproductive hormone levels or their menstrual cycles (Mendelson and Mello, 1984). In a review article by Brown and Dobs (2002), the authors state that endocrine changes observed with marijuana are no longer observed with chronic administration and this may be due to drug tolerance.

Reproductive Cancers

The HHS stated that recent studies support a possible association between frequent, long-term marijuana use and increased risk of testicular germ cell tumors. In a hospital-based case-control study, the frequency of marijuana use was compared between testicular germ cell tumor (TGCT) patients (n = 187) and controls (n = 148) (Trabert et al., 2011). TGCT patients were more likely to be frequent marijuana users than controls with an odds ratio (OR) of 2.2 (95% confidence limits of 1.0–5.1) and were less likely to be infrequent or short-term users with odds ratios of 0.5 and 0.6, respectively in comparison to controls (Trabert et al., 2011). The DEA further notes that in two population-based case-control studies (Daling et al., 2009; Lacson et al., 2012), marijuana use was compared between patients diagnosed with TGCT and matched controls in Washington State or Los Angeles County. In both studies, it was reported that TCGT patients were twice as likely as controls to use marijuana. Authors of both studies concluded that marijuana use is associated with an elevated risk of TGCT (Daling et al., 2009; Lacson et al., 2012).

The HHS cited a study (Sarfaraz et al., 2005) demonstrating that WIN 55,212–2 (a mixed CB1/CB2 agonist) induces apoptosis (one form of cell death) in prostate cancer cells and decreases expression of androgen receptors and prostate specific antigens, suggesting a potential therapeutic value for cannabinoid agonists in the treatment of prostate cancer, an androgen-stimulated type of carcinoma.

Other hormones (e.g. Thyroid, Appetite)

In more recent studies, as cited by the HHS, chronic marijuana use by subjects (n = 39) characterized as dependent on marijuana according to the ICD–10 criteria did not affect serum levels of thyroid hormones: TSH (thyrotropin), T4 (thyroxine), and T3 (triiodothyronine) (Bonnet, 2013). With respect to appetite hormones, in a pilot study with HIV-positive males, smoking marijuana dose-dependently increased plasma levels of ghrelin and leptin and decreased plasma levels of peptide YY (Riggs et al., 2012).

The HHS stated that Δ^9-THC reduces binding of the corticosteroid dexamethasone in hippocampal tissue from adrenalectomized rats and acute Δ^9-THC releases corticosterone, with tolerance developing to this effect with chronic administration (Eldridge ≤et al., 1991). These data suggest that Δ^9-THC may interact with the glucocorticoid receptor system.

Immune System

The HHS stated that cannabinoids alter immune function but that there can be differences between the effects of synthetic, natural, and endogenous cannabinoids (Croxford and Yamamura, 2005; Tanasescu and Constantinescu, 2010).

The HHS noted that there are conflicting results in animal and human studies with respect to cannabinoid effects on immune functioning in subjects with compromised immune systems. Abrams et al. (2003) examined the effects of marijuana and Δ^9-THC in 62 HIV–1-infected patients. Subjects received one of three treatments, three times a day: smoked marijuana cigarette containing 3.95% Δ^9-THC, oral tablet containing Δ^9-THC (2.5 mg oral dronabinol), or oral placebo. There were no changes in CD4+ and CD8+ cell counts, HIV RNA levels, or protease inhibitor levels in any of the treatment groups (Abrams et al., 2003). Therefore, use of cannabinoids showed no short-term adverse virologic effects in individuals with compromised immune systems. Conversely, Roth et al. (2005) reported that in immunodeficient mice implanted with human blood cells infected with HIV, exposure to Δ^9-THC *in vivo* suppresses immune function, increases HIV co-receptor expression, and acts as a cofactor to enhance HIV replication.

The DEA notes two recent clinical studies reporting a decrease in cytokine and interleukin levels following marijuana use. Keen et al. (2014) compared the differences in the levels of IL–6 (interleukin-6), a proinflammatory cytokine, amongst non-drug users (n = 78), marijuana only users (n = 46) and marijuana plus other drug users (n = 45) in a community-based sample of middle-aged African Americans (Keen et al., 2014). After adjusting for confounders, analyses revealed that lifetime marijuana only users had significantly lower IL–6 levels than the nonuser group. Further, Sexton et al. (2014) compared several immune parameters in healthy individuals and subjects with multiple sclerosis (MS) and found that the chronic use of marijuana resulted in reduced monocyte migration, and decreased levels of CCL2 and IL–17 in both healthy and MS groups.

The DEA also notes a review suggesting that Δ^9-THC suppresses the immune responses in experimental animal models and *in vitro* and that these changes may be primarily mediated through the CB2 cannabinoid receptor (Eisenstein and Meissler, 2015).

Factor 3: The State of the Current Scientific Knowledge Regarding the Drug or Substance

Chemistry

The HHS stated that marijuana, also known as *Cannabis sativa L.,* is part of the Cannabaceae plant family and is one of the oldest cultivated crops. The term ''marijuana'' is generally used to refer to a mixture of the dried flowering tops and leaves from *Cannabis.* Marijuana users primarily smoke the marijuana leaves, but individuals also ingest marijuana through food infused with marijuana and its extracts. *Cannabis sativa* is the primary species of *Cannabis* that is illegally marketed in the United States. Marijuana is one of three major derivatives sold as separate illicit products, the other two being hashish and hash oil. Hashish is composed of the dried and compressed cannabinoid-rich resinous material of *Cannabis* and is found as balls and cakes as well as other forms. Individuals may break off pieces and place them into a pipe to smoke. Hash oil, a viscous brown or amber colored liquid, is produced by solvent extraction of cannabinoids from *Cannabis* and contains approximately 50% cannabinoids. One to two drops of hash oil on a cigarette has been reported to produce the equivalent of a single marijuana cigarette (DEA, 2015).

Different marijuana samples are derived from numerous cultivated strains and may have different chemical compositions including levels of Δ^9-THC and other cannabinoids (Appendino et al., 2011). A consequence of having different chemical compositions in the various marijuana samples is that there will be significant differences in safety, biological, pharmacological, and toxicological profiles and therefore, according to the HHS, all *Cannabis* strains cannot be considered collectively because of the variations in chemical composition. Furthermore, the concentration of Δ^9-THC and other cannabinoids present in marijuana may vary due to growing conditions and processing of the plant after harvesting. For example, the plant parts collected such as flowers, leaves and stems can influence marijuana's potency, quality, and purity (Adams and Martin, 1996; Agurell et al., 1984; Mechoulam, 1973). Variations in marijuana harvesting have resulted in potencies ranging from a low of 1 to 2% up to a high of 17% as indicated by cannabinoid content. The concentration of Δ^9-THC averages approximately 12% by weight in a typical marijuana mixture of leaves and stems. However, some specifically grown and selected marijuana samples can contain 15% or greater Δ^9-THC (Appendino et al., 2011). As a result, the Δ^9-THC content in a 1 gram marijuana cigarette can range from as little as 3 milligrams to 150 milligrams or more. In a systematic review conducted by Cascini et al. (2012), it was reported that marijuana's Δ^9-THC content has increased significantly from 1979–2009.

Since there is considerable variability in the cannabinoid concentrations and chemical constituency among marijuana samples, the interpretation of clinical data with marijuana is complicated. A primary issue is the lack of consistent concentrations of Δ^9-THC and other substances in marijuana which complicates the interpretation of the effects of different marijuana constituents. An added issue is that the non-cannabinoid components in marijuana may potentially modify the overall pharmacological and toxicological properties of various marijuana strains and products.

Various *Cannabis* strains contain more than 525 identified natural constituents including cannabinoids, 21 (or 22) carbon terpenoids found in the plant, as well as their carboxylic acids, analogues, and transformation products (Agurell et al., 1984; 1986; Mechoulam, 1973; Appendino et al., 2011). To date, more than 100 cannabinoids have been characterized (ElSohly and Slade, 2005; Radwan et al., 2009; Appendino et al., 2011), and most major cannabinoid compounds occurring naturally have been identified. There are still new and comparably more minor cannabinoids being characterized (Pollastro et al., 2011). The majority of the cannabinoids are found in *Cannabis.* One study reported accumulation of two cannabinoids, cannabigerol and its corresponding acid, in *Helichrysum* (*H. umbraculigerum*) which is a non-*Cannabis* source (Appendino et al., 2011).

Of the cannabinoids found in marijuana, Δ^9-THC (previously known as Δ^1-THC) and delta-8-tetrahydrocannabinol (Δ^8-THC, Δ^6-THC) have been demonstrated to produce marijuana's psychoactive effects. Psychoactive effects from marijuana usage have been mainly attributed to Δ^9-THC because Δ^9-THC is present in significantly more quantities than Δ^8-THC in most marijuana varieties. There are only a few marijuana strains that contain Δ^8-THC in significant amounts (Hively et al., 1966). Δ^9-THC is an optically active resinous substance that is extremely lipophilic. The chemical name for Δ^9-THC is (6a*R*-trans)-6a,7,8,10a-tetrahydro-6,6,9-trimethyl-3-pentyl-6*H*-dibenzo-[b,d]pyran-1-ol, or (−)-delta9-(trans)-tetrahydrocannabinol. The (−)-trans Δ^9-THC isomer is pharmacologically 6 to 100 times more potent than the (+)-trans isomer (Dewey et al., 1984).

Other relatively well-characterized cannabinoids present in marijuana include cannabidiol (CBD), cannabichromene (CBC), and cannabinol (CBN). CBD and CBC are major cannabinoids in marijuana and are both lipophilic. The chemical name for CBD is 2-[(1*R*,6*R*)-3-methyl-6-prop-1-en-2-ylcyclohex-2-en-1-yl]-5-pentylbenzene-1,3-diol and the chemical name for CBC is 2-methyl-2-(4-methylpent-3-enyl)-7-pentyl-5-chromenol. CBN is a minor naturally-occurring cannabinoid with weak psychoactivity and is also a major metabolite of Δ^9-THC. The chemical name for CBN is 6,6,9-trimethyl-3-pentyl-benzo[c]chromen-1-ol.

In summary, marijuana has several strains with high variability in the concentrations of Δ^9-THC, the main psychoactive component, as well as other cannabinoids and compounds. Marijuana is not a single chemical and does not have a consistent and reproducible chemical profile with predictable or consistent clinical effects. In the HHS recommendation for marijuana scheduling (HHS, 2015), it was recommended that investigators consult a guidance for industry entitled, *Botanical Drug Products,*[45] which provides information on the approval of botanical drug products. Specifically, in order to investigate marijuana in support of a New Drug Application (NDA), clinical studies under an Investigational New Drug (IND) application should include "consistent batches of a particular marijuana product for [a] particular disease." (HHS, 2015). Furthermore, the HHS noted that investigators must provide data meeting the requirements for new drug approval as stipulated in 21 CFR 314.50 (HHS, 2015).

Human Pharmacokinetics

Pharmacokinetics of marijuana in humans is dependent on the route of administration and formulation (Adams and Martin, 1996; Agurell et al., 1984; Agurell et al., 1986). Individuals primarily smoke marijuana as a cigarette (weighing between 0.5 and 1 gram) or in a pipe. More recently, vaporizers have been used as another means for individuals to inhale marijuana. Marijuana may also be ingested orally in foods or as an extract in ethanol or other solvents. Pharmacokinetic studies with marijuana focused on evaluating the absorption, metabolism, and elimination profile of Δ^9-THC and other cannabinoids (Adams and Martin, 1996; Agurell et al., 1984; Agurell et al., 1986).

Absorption and Distribution of Inhaled Marijuana Smoke

There is high variability in the pharmacokinetics of Δ^9-THC and other cannabinoids from smoked marijuana due to differences in individual smoking behavior even under controlled experimental conditions (Agurell et al., 1986; Herning et al., 1986; Huestis et al., 1992a). Experienced marijuana users can titrate and regulate the dose by holding marijuana smoke in their lungs for an extended period of time resulting in increased psychoactive effects by prolonging absorption of the smoke. This property may also help explain why there is a poor correlation between venous levels of Δ^9-THC and the intensity of effects and intoxication (Agurell et al., 1986; Barnett et al., 1985; Huestis et al., 1992a). The HHS recommended that puff and inhalation volumes should be tracked in experimental studies because the concentration of cannabinoids can vary at different stages of smoking.

Δ^9-THC from smoked marijuana is rapidly absorbed within seconds. Psychoactive effects are observed immediately following absorption with measurable neurological and behavioral changes for up to 6 hours (Grotenhermen, 2003; Hollister, 1986; Hollister, 1988). Δ^9-THC is distributed to the brain in a rapid and efficient manner. Bioavailability of Δ^9-THC from marijuana (from a cigarette or pipe) ranges from 1 to 24% with the fraction absorbed rarely exceeding 10 to 20% (Agurell et al., 1986; Hollister, 1988). The low and variable bioavailability of Δ^9-THC is due to loss in side-stream smoke, variation in individual smoking behaviors and experience, incomplete absorption of inhaled smoke, and metabolism in lungs (Herning et al., 1986; Johansson et al., 1989). After cessation of smoking, Δ^9-THC venous levels decline within minutes and continue to decline to about 5% to 10% of the peak level within an hour (Agurell et al., 1986; Huestis et al., 1992a; Huestis et al., 1992b).

Absorption and Distribution of Orally Administered Marijuana

Following oral administration of Δ^9-THC or marijuana, onset of effects start within 30 to 90 minutes, peak after 2 to 3 hours and effects remain for 4 to 12 hours (Grotenhermen, 2003; Adams and Martin, 1996; Agurell et al., 1984; Agurell et al., 1986). Dose titration of Δ^9-THC from orally ingested marijuana is difficult for users in comparison to smoked or inhaled marijuana due to the delay in the onset of effects. Oral bioavailability of Δ^9-THC, either in its pure form or in marijuana, is low and variable with a range from 5% to 20% (Agurell et al., 1984; Agurell et al., 1986). There is also inter- and intra-subject variability of orally administered Δ^9-THC under experimental conditions and even under repeated dosing experiments (HHS, 2015). The HHS noted that in bioavailability studies using radiolabeled Δ^9-THC, Δ^9-THC plasma levels following oral administration of Δ^9-THC were low relative to plasma levels after inhaled or intravenously administered Δ^9-THC. The low and variable bioavailability of orally administered Δ^9-THC is due to first pass hepatic elimination from blood and erratic absorption from stomach and bowel (HHS, 2015).

Metabolism and Excretion of Cannabinoids From Marijuana

Studies evaluating cannabinoid metabolism and excretion focused on Δ^9-THC because it is the primary psychoactive component in marijuana.

Δ^9-THC is metabolized via microsomal hydroxylation and oxidation to both active and inactive metabolites (Lemberger et al., 1970; Lemberger et al., 1972a; Lemberger et al., 1972b; Agurell et al., 1986; Hollister, 1988). Metabolism of Δ^9-THC is consistent among frequent and infrequent marijuana users (Agurell et al., 1986). The primary active metabolite of Δ^9-THC following oral ingestion is 11-hydroxy-Δ^9-THC which is equipotent to Δ^9-THC in producing marijuana-like subjective effects (Agurell et al., 1986; Lemberger and Rubin, 1975). Metabolite levels following oral administration may be greater than that of Δ^9-THC and may contribute greatly to the pharmacological effects of oral Δ^9-THC or marijuana.

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[45] Available at *http://www.fda.gov/Drugs/default.htm* under Guidance (Drugs).

Plasma clearance of Δ^9-THC approximates hepatic blood flow at a rate of approximately 950 ml/min or greater. Rapid clearance of Δ^9-THC from blood is primarily due to redistribution to other tissues in the body rather than to metabolism (Agurell et al., 1984; Agurell et al., 1986). Outside of the liver, metabolism in most tissues is considerably slow or does not occur. The elimination half-life of Δ^9-THC ranges from 20 hours to between 10 and 13 days (Hunt and Jones, 1980). Lemberger et al. (1970) reported that the half-life of Δ^9-THC ranged from 23–28 hours in heavy marijuana users and up to 60 to 70 hours in naïve users. The long elimination half-life of Δ^9-THC is due to slow release of Δ^9-THC and other cannabinoids from tissues and subsequent metabolism. Inactive carboxy metabolites of Δ^9-THC have terminal half-lives of 50 hours to 6 days or more and serve as long-term markers in urine tests for marijuana use.

Most of the absorbed Δ^9-THC dose is eliminated in the feces and about 33% in urine. The glucuronide metabolite of Δ^9-THC is excreted as the major urine metabolite along with 18 non-conjugated metabolites (Agurell et al., 1986).

Research Status and Test of Currently Accepted Medical Use for Marijuana

According to the HHS, there are numerous human clinical studies with marijuana in the United States under FDA-regulated IND applications. Results of small clinical exploratory studies have been published in the medical literature. Approval of a human drug for marketing, however, is contingent upon FDA approval of a New Drug Application (NDA) or a Biologics License Application (BLA). According to the HHS, the FDA has not approved any drug product containing marijuana for marketing.

The HHS noted that a drug may be found to have a medical use in treatment in the United States for purposes of the CSA if the drug meets the five elements described by the DEA in 1992. Those five elements "are both necessary and sufficient to establish a prima facie case of currently accepted medical use" in treatment in the United States." (57 FR 10499, 10504 (March 26, 1992)). This five-element test, which the HHS and DEA have utilized in all such analyses for more than two decades, has been upheld by the Court of Appeals. *ACT,* 15 F.3d at 1135. The five elements that characterize "currently accepted medical use" for a drug are summarized here and expanded upon in the discussion below:

1. *The drug's chemistry must be known and reproducible;*
2. *There must be adequate safety studies;*
3. *There must be adequate and well-controlled studies proving efficacy;*
4. *The drug must be accepted by qualified experts; and*
5. *Scientific evidence must be widely available.*

In its review (HHS, 2015), the HHS evaluated the five elements with respect to the currently available research for marijuana. The HHS concluded that marijuana does not meet any of the five elements—all of which must be demonstrated to find that a drug has a "currently accepted medical use." A brief summary of the HHS's evaluation is provided below.

Element #1: The drug's chemistry must be known and reproducible.

"The substance's chemistry must be scientifically established to permit it to be reproduced into dosages which can be standardized. The listing of the substance in a current edition of one of the official compendia, as defined by section 201(j) of the Food, Drug and Cosmetic Act, 21 U.S.C. 321(j), is sufficient generally to meet this requirement." 57 FR 10499, 10506 (March 26, 1992).

As defined by the CSA, marijuana includes all species of the genus *Cannabis,* including all strains therein.[46] Chemical constituents including Δ^9-THC and other cannabinoids vary significantly in marijuana samples derived from different strains (Appendino et al., 2011). As a result, there will be significant differences in safety, biological, pharmacological, and toxicological parameters amongst the various marijuana samples. Due to the variation of the chemical composition in marijuana samples, it is not possible to reproduce a standardized dose when considering all strains together. The HHS does advise that if a specific *Cannabis* strain is cultivated and processed under controlled conditions, the plant chemistry may be consistent enough to derive reproducible and standardized doses.

Element #2: There must be adequate safety studies.

"There must be adequate pharmacological and toxicological studies, done by all methods reasonably applicable, on the basis of which it could fairly and responsibly be concluded, by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, that the substance is safe for treating a specific, recognized disorder." 57 FR 10499, 10506 (March 26, 1992).

The HHS stated that there are no adequate safety studies on marijuana. As indicated in their evaluation of Element #1, the considerable variation in the chemistry of marijuana complicates the safety evaluation. The HHS concluded that marijuana does not satisfy Element #2 for having adequate safety studies such that medical and scientific experts may conclude that it is safe for treating a specific ailment.

Element #3: There must be adequate and well-controlled studies of efficacy.

"There must be adequate, well-controlled, well-designed, well-conducted and well-documented studies, including clinical investigations, by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, on the basis of which it could be fairly and responsibly concluded by such exports that the substance will have the intended effect in treating a specific, recognized disorder." 57 FR 10499, 10506 (March 26, 1992).

As indicated in the HHS's review of marijuana (HHS, 2015), there are no adequate or well-controlled studies that prove marijuana's efficacy. The FDA independently reviewed (FDA, 2015) publicly available clinical studies on marijuana published prior to February 2013 to determine if there were appropriate studies to determine marijuana's efficacy (please refer to FDA, 2015 and HHS, 2015 for more details). After review, the FDA determined that out of the identified articles, including those identified through a search of bibliographic references and 566 abstracts located on PubMed, 11 studies met the *a priori* selection criteria, including placebo control and double-blinding. FDA and HHS critically reviewed each of the 11 studies to determine if the studies met accepted scientific standards. FDA and HHS concluded that these studies do not "currently prove efficacy of marijuana" for any therapeutic indication due to limitations in the study designs. The HHS indicated that these studies could be used as proof of concept studies, providing preliminary evidence on a proposed hypothesis involving a drug's effect.

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[46] Although the CSA definition of marijuana refers only to the species "Cannabis sativa L.," federal courts have consistently ruled that all species of the genus cannabis are included in this definition. *See United States* v. *Kelly,* 527 F.2d 961, 963–964 (9th Cir. 1976) (collecting and examining cases). The Single Convention (article 1, par. 1(c)) likewise defines the "cannabis plant" to mean "any plant of the genus Cannabis." As explained above in the attachment titled "Preliminary Note Regarding Treaty Considerations," 21 U.S.C. 811(d)(1) provides that, where a drug is subject to control under the Single Convention, the DEA Administrator must control the drug under the schedule he deems most appropriate to carry out such treaty obligations, without regard to the findings required by 21 U.S.C. 811(a) or 812(b) and without regard to the procedures prescribed by 21 U.S.C. 811(a) and (b).

Element #4: The drug must be accepted by qualified experts.

"[A] consensus of the national community of experts, qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, accepts the safety and effectiveness of the substance for use in treating a specific, recognized disorder. A material conflict of opinion among experts precludes a finding of consensus." 57 FR 10499, 10506 (March 26, 1992).

The HHS concluded that there is currently no evidence of a consensus among qualified experts that marijuana is safe and effective in treating a specific and recognized disorder. The HHS indicated that medical practitioners who are not experts in evaluating drugs cannot be considered qualified experts (HHS, 2015; 57 FR 10499, 10505). Further, the HHS noted that the 2009 American Medical Association (AMA) report entitled, "Use of Cannabis for Medicinal Purposes" does not conclude that there is a currently accepted medical use for marijuana. HHS also pointed out that state-level "medical marijuana" laws do not provide evidence of such a consensus among qualified experts.

Element #5: The scientific evidence must be widely available.

"In the absence of NDA approval, information concerning the chemistry, pharmacology, toxicology, and effectiveness of the substance must be reported, published, or otherwise widely available, in sufficient detail to permit experts, qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, to fairly and responsibly conclude the substance is safe and effective for use in treating a specific, recognized disorder." 57 FR 10499, 10506 (March 26, 1992).

The HHS concluded that the currently available data and information on marijuana is not sufficient to allow scientific scrutiny of the chemistry, pharmacology, toxicology, and effectiveness. In particular, scientific evidence demonstrating the chemistry of a specific *Cannabis* strain that could provide standardized and reproducible doses is not available.

Petitioners' Major Comments in Relation to Factor 3 and the Government's Responses

(1) The petitioner states on page 2 of the petition, *"Marijuana has accepted medical use in the United States. Thirteen states accept the safety of marijuana for medical use . . . . Marijuana has been accepted as having medical use by dozens of professional medical and nursing organizations throughout the U.S. . . . Even the American Medical Association has now accepted the safety and efficacy of cannabinoid medicines and supports removal of marijuana from schedule I of the CSA in order to support further research."*

As noted above, the HHS concluded that there is currently no evidence of a consensus among qualified experts that marijuana is safe and effective in treating a specific and recognized disorder, as required by the established standards. HHS pointed out that state-level "medical marijuana" laws do not provide evidence of such a consensus among qualified experts. HHS also indicated that medical practitioners who are not experts in evaluating drugs cannot be considered qualified experts (HHS, 2015; 57 FR 10499, 10505).

Further, the HHS pointed out that the 2009 AMA report entitled, "Use of Cannabis for Medicinal Purposes" does not conclude that there is a currently accepted medical use for marijuana. Instead, the AMA, like several other professional and medical associations, recommended further testing with marijuana to determine its medicinal value. The AMA official policy on medicinal use of marijuana is as follows: "*Our AMA urges that marijuana's status as a federal Schedule I controlled substance be reviewed with the goal of facilitating the conduct of clinical research and development of cannabinoid-based medicines, and alternative delivery methods. This should not be viewed as an endorsement of state-based medical cannabis programs, the legalization of marijuana, or that scientific evidence on the therapeutic use of cannabis meets the current standards for a prescription drug product.*" (AMA, 2009). The DEA further notes that the 2013 AMA House of Delegates report states that, "*cannabis is a dangerous drug and as such is a public health concern.*" (AMA, 2013).

(2) The petitioner asserts on page 3 of the petition that, *"Several recent studies of smoked marijuana have confirmed the safety and efficacy of smoked marijuana for medical use."*

The HHS, in its scientific and medical evaluation, reviewed marijuana clinical studies evaluating therapeutic properties and concluded that there is not enough data to confirm the safety and efficacy of smoked marijuana for use in treating a specific and recognized disorder. Relevant to efficacy, for instance, the HHS concluded, for instance, that "smoking marijuana currently has not been shown to allow delivery of consistent and reproducible doses," and that the bioavailability of the delta-9 -THC from marijuana in a cigarette or pipe can range from 1 percent to 24 percent with the fraction absorbed rarely exceeding 10 to 20%. Issues relating to the safety of smoked marijuana were discussed above in Factor 2.

(3) On page 3, the petitioner states that *"marijuana has been determined to be safe for use under medical supervision by the DEA's own administrative law judge."*

As described above, in the absence of NDA or ANDA approval, DEA has established a five-element test for determining whether the drug has a currently accepted medical use in treatment in the United States. 57 FR 10499, 10506 (March 26, 1992)). *See also ACT,* 15 F.3d at 1135. In response to this petition, HHS concluded, and DEA agrees, that the scientific evidence is insufficient to demonstrate that marijuana has a currently accepted medical use under the five-element test. The evidence was insufficient in this regard also when the DEA considered petitions to reschedule marijuana in 1992 (57 FR 10499), in 2001 (66 FR 20038), and in 2011 (76 FR 40552). Little has changed since 2011 with respect to the lack of clinical evidence necessary to establish that marijuana has a currently accepted medical use. No studies have scientifically assessed the efficacy and full safety profile of marijuana for any specific medical condition.

Factor 4: Its History and Current Pattern of Abuse

Marijuana continues to be the most widely used illicit drug. In 2013, an estimated 24.6 million Americans age 12 or older were current (past month) illicit drug users. Of those, 19.8 million were current (past month) marijuana users. As of 2013, an estimated 114.7 million Americans age 12 and older had used marijuana or hashish in their lifetime and 33.0 million had used it in the past year.

According to the NSDUH estimates, 3.0 million people age 12 or older used an illicit drug for the first time in 2014. Marijuana initiates totaled 2.6 million in 2014. Nearly half (46.8%) of the 2.6 million new users were less than 18 years of age. In 2014, marijuana was used by 82.2% of current (past month) illicit drug users. In 2014, among past year marijuana users age 12 or older, 18.5% used marijuana on 300 or more days within the previous 12 months. This translates into 6.5 million people using marijuana on a daily or almost daily basis over a 12-month period, a significant increase from the 3.1 million daily or almost daily users in 2006 and from the 5.7 million in just the previous year. In 2014, among past month marijuana users, 41.6% (9.2 million people) used the drug on 20 or more days in the past month, a significant increase from the 8.1 million in 2013.

Marijuana is also the illicit drug with the highest numbers of past year dependence or abuse in the U.S. population. According to the 2014 NSDUH report, of the 7.1 million persons aged 12 or older who were classified with illicit drug dependence or abuse, 4.2 million of them abused or were dependent on marijuana (representing 59.0% of all those classified with illicit drug dependence or abuse and 1.6% of the total U.S. non-institutionalized population aged 12 or older).

According to the 2015 Monitoring the Future (MTF) survey, marijuana is used by a large percentage of American youths, and is the most commonly used illicit drug among American youth. Among students surveyed in 2015, 15.5% of 8th graders, 31.1% of 10th graders, and 44.7% of 12th graders reported that they had used marijuana in their lifetime. In addition, 11.8%, 25.4%, and 34.9% of 8th, 10th, and 12th graders, respectively, reported using marijuana in the past year. A number of high school students reported daily use in the past month, including 1.1%, 3.0%, and 6.0% of 8th, 10th, and 12th graders, respectively.

The prevalence of marijuana use and abuse is also indicated by criminal investigations for which drug evidence was analyzed in federal, state, and local forensic laboratories, as discussed above in Factor 1. The National Forensic Laboratory System (NFLIS), a DEA program, systematically collects drug identification results and associated information from drug cases submitted to and analyzed by federal, state, and local forensic laboratories. NFLIS data shows that marijuana was the most frequently identified drug from January 2001 through December 2014. In 2014, marijuana accounted for 29.3% (432,989) of all drug exhibits in NFLIS.

The high consumption of marijuana is being fueled by increasing amounts of domestically grown marijuana as well as increased amounts of foreign source marijuana being illicitly smuggled into the United States. In 2014, the Domestic Cannabis Eradication and Suppression Program (DCE/SP) reported that 3,904,213 plants were eradicated in outdoor cannabis cultivation areas compared to 2,597,798 in 2000, as shown above in Table 3. Significant quantities of marijuana were also eradicated from indoor cultivation operations. There were 396,620 indoor plants eradicated in 2014 compared to 217,105 eradicated in 2000. As shown in Table 2 above, in 2014, the National Seizure System (NSS) reported seizures of 1,767,741 kg of marijuana.

Factor 5: The Scope, Duration, and Significance of Abuse

Abuse of marijuana is widespread and significant. As previously noted, according to the NSDUH, in 2014, an estimated 117.2 million Americans (44.2%) age 12 or older had used marijuana or hashish in their lifetime, 35.1 million (13.2%) had used it in the past year, and 22.2 million (8.4%) had used it in the past month. Past year and past month marijuana use has increased significantly since 2013. Past month marijuana use is highest among 18–21 year olds and it declines among those 22 years of age and older. In 2014, an estimated 18.5% of past year marijuana users age 12 or older used marijuana on 300 or more days within the past 12 months. This translates into 6.5 million persons using marijuana on a daily or almost daily basis over a 12-month period. In 2014, an estimated 41.6% (9.2 million) of past month marijuana users age 12 or older used the drug on 20 or more days in the past month (SAMHSA, NSDUH). Chronic use of marijuana is associated with a number of health risks (see Factors 2 and 6).

Furthermore, the average percentage of Δ^9-THC in seized marijuana has increased over the past two decades (The University of Mississippi Potency Monitoring Project). Additional studies are needed to clarify the impact of greater potency, but one study shows that higher levels of Δ^9-THC in the body are associated with greater psychoactive effects (Harder and Rietbrock, 1997), which can be correlated with higher abuse potential (Chait and Burke, 1994).

TEDS data show that in 2013, marijuana/hashish was the primary substance of abuse in 16.8% of all admissions to substance abuse treatment among patients age 12 and older. TEDS data also show that marijuana/hashish was the primary substance of abuse for 77.0% of all 12- to 14-year-olds admitted for drug treatment and 75.5% of all 15- to 17-year-olds admitted for drug treatment in 2013. Among the 281,991 admissions to drug treatment in 2013 in which marijuana/hashish was the primary drug, the average age at admission was 25 years and the peak age cohort was 15 to 17 years (22.5%). Thirty-nine percent of the 281,991 primary marijuana/hashish admissions (35.9%) were under the age of 20.

In summary, the recent statistics from these various surveys and databases (see Factor 1 for more details) demonstrate that marijuana continues to be the most commonly used illicit drug, with large incidences of heavy use and dependence in teenagers and young adults.

Factor 6: What, if Any, Risk There Is to the Public Health

In its recommendation, the HHS discussed public health risks associated with acute and chronic marijuana use in Factor 6. Public health risks as measured by emergency department visits and drug treatment admissions are discussed by HHS and DEA in Factors 1, 4, and 5. Similarly, Factor 2 discusses marijuana's pharmacology and presents some of the adverse health effects associated with use. Marijuana use may affect the physical and/or psychological functioning of an individual user, but may also have broader public impacts including driving impairments and fatalities from car accidents.

Risks From Acute Use of Marijuana

As discussed in the HHS review document (HHS, 2015), acute usage of marijuana impairs psychomotor performance including motor control and impulsivity, risk taking and executive function (Ramaekers et al., 2004; Ramaekers et al., 2006). In a minority of individuals using marijuana, dysphoria, prolonged anxiety, and psychological distress may be observed (Haney et al., 1999). The DEA further notes a recent review of acute marijuana effects (Wilkinson et al., 2014) that reported impaired neurological function including altered perception, paranoia, delayed response time, and memory deficits.

In its recommendation, HHS references a meta-analysis conducted by Li et al. (2012) where the authors concluded that psychomotor impairments associated with acute marijuana usage have also been associated with increased risk of car accidents with individuals experiencing acute marijuana intoxication (Li et al., 2012; HHS, 2015). The DEA further notes more recent studies examining the risk associated with marijuana use and driving. Younger drivers (under 21) have been characterized as the highest risk group associated with marijuana use and driving (Whitehill et al., 2014). Furthermore, in 2013, marijuana was found in 13% of the drivers involved in automobile-related fatal accidents (McCartt, 2015). The potential risk of automobile accidents associated with marijuana use appears to be increasing since there has been a steady increase in individuals intoxicated with marijuana over the past 20 years (Wilson et al., 2014). However, a recent study commissioned by the National Highway Traffic Safety Administration (NHTSA) reported that when adjusted for confounders (*e.g.,* alcohol use, age, gender, ethnicity), there was not a significant increase in crash risk (fatal and nonfatal, n = 2,682) associated with marijuana use (Compton and Berning, 2015).

The DEA also notes recent studies examining unintentional exposures of children to marijuana (Wang et al., 2013; 2014). Wang et al. (2013) reviewed emergency department (ED) visits at a children's hospital in Colorado from January 1, 2005 to December 31, 2011. As stated by the authors, in 2000 Colorado passed Amendment 20 which allowed for the use of marijuana. Following the passage of "a new Justice Department policy" instructing "federal prosecutors not to seek arrest of medical marijuana users and suppliers as long as they conform to state laws" (as stated in Wang et al., 2013), 14 patients in Colorado under the age of 12 were admitted to the ED for the unintended use of marijuana over a 27 month period. Prior to the passage of this policy, from January 1, 2005 to September 30, 2009 (57 months), there were no pediatric ED visits due to unintentional marijuana exposure (Wang et al., 2013). The DEA also notes a larger scale evaluation of pediatric exposures using the National Poison Data System (Wang et al., 2014). That study reported that there were 985 unintentional marijuana exposures in children (9 years and younger) between January 1, 2005 to December 31, 2011. The authors stratified the ED visits by states with laws allowing medical use of marijuana, states transitioning to legalization for medical use, and states with no such laws. Out of the 985 exposures, 495 were in non-legal states (n=33 states), 93 in transitional states (n=8 states), and 396 in "legal" states (n=9 states). The authors reported that there was a twofold increase (OR = 2.1) in moderate or major effects in children with unintentional marijuana use and a threefold increase (OR = 3.4) in admissions to critical care units in states allowing medical use of marijuana, in comparison to non-legal states.

Risks Associated With Chronic Use of Marijuana

The HHS noted that a major risk from chronic marijuana use is a distinctive withdrawal syndrome, as described in the 2013 DSM–5. The HHS analysis also quoted the following description of risks associated with marijuana [cannabis] abuse from the DSM–5:

> *Individuals with cannabis use disorder may use cannabis throughout the day over a period of months or years, and thus may spend many hours a day under the influence. Others may use less frequently, but their use causes recurrent problems related to family, school, work, or other important activities (e.g., repeated absences at work; neglect of family obligations). Periodic cannabis use and intoxication can negatively affect behavioral and cognitive functioning and thus interfere with optimal performance at work or school, or place the individual at increased physical risk when performing activities that could be physically hazardous (e.g. driving a car; playing certain sports; performing manual work activities, including operating machinery). Arguments with spouses or parents over the use of cannabis in the home, or its use in the presence of children, can adversely impact family functioning and are common features of those with cannabis use disorder. Last, individuals with cannabis use disorder may continue using marijuana despite knowledge of physical problems (e.g. chronic cough related to smoking) or psychological problems (e.g. excessive sedation or exacerbation of other mental health problems) associated with its use.* (HHS 2015, page 34).

The HHS stated that chronic marijuana use produces acute and chronic adverse effects on the respiratory system, memory and learning. Regular marijuana smoking can produce a number of long-term pulmonary consequences, including chronic cough and increased sputum (Adams and Martin, 1996), and histopathologic abnormalities in bronchial epithelium (Adams and Martin, 1996).

Marijuana as a "Gateway Drug"

The HHS reviewed the clinical studies evaluating the gateway hypothesis in marijuana and found them to be limited. The primary reasons were: (1) Recruited participants were influenced by social, biological, and economic factors that contribute to extensive drug abuse (Hall and Lynskey, 2005), and (2) most studies testing the gateway drug hypothesis for marijuana use the determinative measure *any use of an illicit drug* rather than applying DSM–5 criteria for drug abuse or dependence (DSM–5, 2013).

The HHS cited several studies where marijuana use did not lead to other illicit drug use (Kandel and Chen, 2000; von Sydow et al., 2002; Nace et al., 1975). Two separate longitudinal studies with adolescents using marijuana did not demonstrate an association with use of other illicit drugs (Kandel and Chen, 2000; von Sydow et al., 2002).

It was noted by the HHS that, when evaluating the gateway hypothesis, differences appear when examining use versus abuse or dependence of other illicit drugs. Van Gundy and Rebellon (2010) reported that there was a correlation between marijuana use in adolescence and other illicit drug use in early adulthood, but when examined in terms of drug abuse of other illicit drugs, age-linked stressors and social roles were confounders in the association. Degenhardt et al. (2009) reported that marijuana use often precedes use of other illicit drugs, but dependence involving drugs other than marijuana frequently correlated with higher levels of illicit drug abuse. Furthermore, Degenhardt et al. (2010) reported that in countries with lower prevalence of marijuana usage, use of other illicit drugs before marijuana was often documented.

Based on these studies among others, the HHS concluded that although many individuals with a drug abuse disorder may have used marijuana as one of their first illicit drugs, this does not mean that individuals initiated with marijuana inherently will go on to become regular users of other illicit drugs.

Factor 7: Its Psychic or Physiological Dependence Liability

Physiological (Physical) Dependence in Humans

The HHS stated that heavy and chronic use of marijuana can lead to physical dependence (DSM–5, 2013; Budney and Hughes, 2006; Haney et al., 1999). Tolerance is developed following repeated administration of marijuana and withdrawal symptoms are observed as following discontinuation of marijuana usage (HHS, 2015).

The HHS mentioned that tolerance can develop to some of marijuana's effects, but does not appear to develop with respect to the psychoactive effects. It is believed that lack of tolerance to psychoactive effects may relate to electrophysiological data demonstrating that chronic Δ^9-THC administration does not affect increased neuronal firing in the ventral tegmental area, a brain region that plays a critical role in drug reinforcement and reward (Wu and French, 2000). Humans can develop tolerance to marijuana's cardiovascular, autonomic, and behavioral effects (Jones et al., 1981). Tolerance to some behavioral effects appears to develop with heavy and chronic use, but not with occasional usage. Ramaekers et al. (2009) reported that following acute administration of marijuana, occasional marijuana users still exhibited impairments in tracking and attention tasks whereas performance of heavy users on the these tasks was not affected. In a follow-up study with the same subjects that participated in the study by Ramaekers et al. (2009), a neurophysiological assessment was conducted where event-related potentials (ERPs) were measured using electroencephalography (EEG) (Theunissen et al., 2012). Similar to the earlier results, the heavy marijuana users (n = 11; average of 340 marijuana uses per year) had no changes in their ERPs with the acute marijuana exposure. However, occasional users (n = 10; average of 55 marijuana uses per year) had significant decreases in the amplitude of an ERP component (categorized as P100) on tracking and attention tasks and ERP amplitude change is indicative of a change in brain activity (Theunissen et al., 2012).

The HHS indicated that down-regulation of cannabinoid receptors may be a possible mechanism for tolerance to marijuana's effects (Hirvonen et al., 2012; Gonzalez et al., 2005; Rodriguez de Fonseca et al., 1994; Oviedo et al., 1993).

As indicated by the HHS, the most common withdrawal symptoms in heavy, chronic marijuana users are sleep difficulties, decreased appetite or weight loss, irritability, anger, anxiety or nervousness, and restlessness (Budney and Hughes, 2006; Haney et al., 1999). As reported by HHS, most marijuana withdrawal symptoms begin within 24–48 hours of discontinuation, peak within 4–6 days, and last for 1–3 weeks.

The HHS pointed out that the American Psychiatric Association's (APA's) Diagnostic and Statistical Manual of Mental Disorders—5 (DSM–5) included a list of withdrawal symptoms following marijuana [cannabis] use (DSM–5, 2013). The DEA notes that a DSM–5 working group report indicated that marijuana withdrawal symptoms were added to DSM–5 (they were not previously included in DSM–IV) because marijuana withdrawal has now been reliably presented in several studies (Hasin et al., 2013). In short, marijuana withdrawal signs are reported in up to one-third of regular users and between 50% and 90% of heavy users (Hasin et al., 2013). According to DSM–5 criteria, in order to be characterized as having marijuana withdrawal, an individual must develop at least three of the seven symptoms within one week of decreasing or stopping the heavy and prolonged use (DSM–5, 2013). These seven symptoms are: (1) Irritability; anger or aggression, (2) nervousness or anxiety, (3) sleep difficulty, (4) decreased appetite or weight loss, (5) restlessness, (6) decreased mood, (7) somatic symptoms causing significant discomfort (DSM–5, 2013).

Psychological (Psychic) Dependence in Humans

High levels of psychoactive effects such as positive reinforcement correlate with increased marijuana abuse and dependence (Scherrer et al., 2009; Zeiger et al., 2010). Epidemiological marijuana use data reported by NSDUH, MTF, and TEDS support this assertion as presented in the HHS 2015 review of marijuana and updated by the DEA. According to the findings in the 2014 NSDUH survey, an estimated 9.2 million individuals 12 years and older used marijuana daily or almost daily (20 or more days within the past month). In the 2015 MTF report, daily marijuana use (20 or more days within the past 30 days) in 8th, 10th, and 12th graders is 1.1%, 3.0%, and 6.0%, respectively.

The 2014 NSDUH report stated that 4.2 million persons were classified with dependence on or abuse of marijuana in the past year (representing 1.6% of the total population age 12 or older, and 59.0% of those classified with illicit drug dependence or abuse) based on criteria specified in the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM–IV). Furthermore, of the admissions to licensed substance abuse facilities, as presented in TEDS, marijuana/hashish was the primary substance of abuse for; 18.3% (352,297) of 2011 admissions; 17.5% (315,200) of 2012 admissions; and 16.8% (281,991) of 2013 admissions. Of the 281,991 admissions in 2013 for marijuana/hashish as the primary substance, 24.3% used marijuana/hashish daily. Among admissions to treatment for marijuana/hashish as the primary substance in 2013, 27.4% were ages 12 to 17 years and 29.7% were ages 20 to 24 years.

Factor 8: Whether the Substance is an Immediate Precursor of a Substance Already Controlled Under the CSA

Marijuana is not an immediate precursor of another controlled substance.

Determination

After consideration of the eight factors discussed above and of the HHS's Recommendation, the DEA finds that marijuana meets the three criteria for placing a substance in schedule I of the CSA under 21 U.S.C. 812(b)(1):

1. Marijuana has a high potential for abuse.

The HHS concluded that marijuana has a high potential for abuse based on a large number of people regularly using marijuana, its widespread use, and the vast amount of marijuana that is available through illicit channels.

Marijuana is the most abused and trafficked illicit substance in the United States. Approximately 22.2 million individuals in the United States (8.4% of the United States population) were past month users of marijuana according to the 2014 NSDUH survey. A 2015 national survey (Monitoring the Future) that tracks drug use trends among high school students showed that by 12th grade, 21.3% of students reported using marijuana in the past month, and 6.0% reported having used it daily in the past month. In 2011, SAMHSA's Drug Abuse Warning Network (DAWN) reported that marijuana was mentioned in 36.4% of illicit drug-related emergency department (ED) visits, corresponding to 455,668 out of approximately 1.25 million visits. The Treatment Episode Data Set (TEDS) showed that 16.8% of non-private substance-abuse treatment facility admissions in 2013 were for marijuana as the primary drug.

Marijuana has dose-dependent reinforcing effects that encourage its abuse. Both clinical and preclinical studies have demonstrated that marijuana and its principle psychoactive constituent, Δ^9-THC, possess the pharmacological attributes associated with drugs of abuse. They function as discriminative stimuli and as positive reinforcers to maintain drug use and drug-seeking behavior. Additionally, use of marijuana can result in psychological dependence.

2. Marijuana has no currently accepted medical use in treatment in the United States.

The HHS stated that the FDA has not approved an NDA for marijuana. The HHS noted that there are opportunities for scientists to conduct clinical research with marijuana and there are active INDs for marijuana, but marijuana does not have a currently accepted medical use in the United States, nor does it have an accepted medical use with severe restrictions.

FDA approval of an NDA is not the sole means through which a drug can be determined to have a "currently accepted medical use" under the CSA. Applying the five-part test summarized below, a drug has a currently accepted medical use if all of the following five elements have been satisfied. As detailed in the HHS evaluation and as set forth below, none of these elements has been fulfilled for marijuana:

i. The drug's chemistry must be known and reproducible

Chemical constituents including Δ^9-THC and other cannabinoids in marijuana vary significantly in different marijuana strains. In addition, the concentration of Δ^9-THC and other cannabinoids may vary between strains. Therefore the chemical composition among different marijuana samples is not reproducible. Due to the variation of the chemical composition in marijuana strains, it is not possible to derive a standardized dose. The HHS does advise that if a specific *Cannabis* strain is cultivated and processed under controlled conditions, the plant chemistry may be consistent enough to derive standardized doses.

ii. There must be adequate safety studies

There are not adequate safety studies on marijuana for use in any specific, recognized medical condition. The considerable variation in the chemistry of marijuana results in differences in safety, biological, pharmacological, and toxicological parameters amongst the various marijuana samples.

iii. There must be adequate and well-controlled studies proving efficacy

There are no adequate and well-controlled studies that determine marijuana's efficacy. In an independent review performed by the FDA of publicly available clinical studies on marijuana (FDA, 2015), FDA concluded that these studies do not have enough information to "*currently prove efficacy of marijuana*" for any therapeutic indication.

iv. The drug must be accepted by qualified experts

At this time, there is no consensus of opinion among experts concerning the medical utility of marijuana for use in treating specific recognized disorders.

v. The scientific evidence must be widely available

The currently available data and information on marijuana is not sufficient to address the chemistry, pharmacology, toxicology, and effectiveness. The scientific evidence regarding marijuana's chemistry with regard to a specific cannabis strain that could be formulated into standardized and reproducible doses is not currently available.

3. There is a lack of accepted safety for use of marijuana under medical supervision.

Currently, there are no FDA-approved marijuana products. The HHS also concluded that marijuana does not have a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions. According to the HHS, the FDA is unable to conclude that marijuana has an acceptable level of safety in relation to its effectiveness in treating a specific and recognized disorder due to lack of evidence with respect to a consistent and reproducible dose that is contamination free. The HHS indicated that marijuana research investigating potential medical use should include information on the chemistry, manufacturing, and specifications of marijuana. The HHS further indicated that a procedure for delivering a consistent dose of marijuana should also be developed. Therefore, the HHS concluded that marijuana does not have an acceptable level of safety for use under medical supervision.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1301

[Docket No. DEA–447]

Applications To Become Registered Under the Controlled Substances Act To Manufacture Marijuana To Supply Researchers in the United States

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Policy statement.

SUMMARY: To facilitate research involving marijuana and its chemical constituents, DEA is adopting a new policy that is designed to increase the number of entities registered under the Controlled Substances Act (CSA) to grow (manufacture) marijuana to supply legitimate researchers in the United States. This policy statement explains how DEA will evaluate applications for such registration consistent with the CSA and the obligations of the United States under the applicable international drug control treaty.

DATES: August 12, 2016.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Background

Reasons for This Policy Statement

There is growing public interest in exploring the possibility that marijuana or its chemical constituents may be used as potential treatments for certain medical conditions. The Federal Food, Drug and Cosmetic Act requires that before a new drug is allowed to enter the U.S. market, it must be demonstrated through adequate and well-controlled clinical trials to be both safe and effective for its intended uses. Congress long ago established this process, recognizing that it was essential to protect the health and welfare of the American people.

Although no drug product made from marijuana has yet been shown to be safe and effective in such clinical trials, DEA—along with the Food and Drug Administration (FDA) and the National Institutes of Health (NIH)—fully supports expanding research into the potential medical utility of marijuana and its chemical constituents.[1]

There are a variety of factors that influence whether and to what extent such research takes place. Some of the key factors—such as funding—are beyond DEA's control.[2] However, one of the ways DEA can help to facilitate research involving marijuana is to take steps, within the framework of the CSA and U.S. treaty obligations, to increase the lawful supply of marijuana available to researchers.

For nearly 50 years, the United States has relied on a single grower to produce marijuana used in research. This grower operates under a contract with the National Institute on Drug Abuse (NIDA). This longstanding arrangement has historically been considered by the U.S. Government to be the best way to satisfy our nation's obligations under the applicable international drug control treaty, as discussed in more detail below. For most of the nearly 50 years that this single marijuana grower arrangement has been in existence, the demand for research-grade marijuana in the United States was relatively limited—and the single grower was able to meet such limited demand. However, in recent years, there has been greater public interest in expanding marijuana-related research, particularly with regard to certain chemical constituents in the plant known as cannabinoids.

The term "cannabinoids" generally refers to those chemicals unique to the cannabis plant (marijuana).[3] To date, more than 100 different cannabinoids have been found in the plant. One such cannabinoid—known as cannabidiol or CBD—has received increased attention in recent years. Although the effects of CBD are not yet fully understood by scientists, and research is ongoing in this area, some studies suggest that CBD may have uses in the treatment of seizures and other neurological disorders. A growing number of researchers have expressed interest in conducting research with extracts of marijuana that have a particular percentage of CBD and other cannabinoids. DEA fully supports research in this area. Based on discussions with NIDA and FDA, DEA has concluded that the best way to satisfy the current researcher demand for a variety of strains of marijuana and cannabinoid extracts is to increase the number of federally authorized marijuana growers. To achieve this result, DEA, in consultation with NIDA and FDA, has developed a new approach to allow additional marijuana growers to apply to become registered with DEA, while upholding U.S. treaty obligations and the CSA. This policy statement explains the new approach, provides details about the process by which potential growers may apply for a DEA registration, and describes the steps they must take to ensure their activity will be carried out in conformity with U.S. treaty obligations and the CSA.

The historical system, under which NIDA relied on one grower to supply marijuana on a contract basis, was designed primarily to supply marijuana for use in federally funded research—not for commercial product development. Thus, under the historical system, there was no clear legal pathway for commercial enterprises to produce marijuana for product development. In contrast, under the new approach explained in this policy statement, persons may become registered with DEA to grow marijuana not only to supply federally funded or other academic researchers, but also for strictly commercial endeavors funded by the private sector and aimed at drug product development. Likewise, under the new approach, should the state of scientific knowledge advance in the future such that a marijuana-derived drug is shown to be safe and effective for medical use, pharmaceutical firms will have a legal means of producing such drugs in the United States—independent of the NIDA contract process.

Legal Considerations

Applicable CSA Provisions

Under the CSA, all persons who seek to manufacture or distribute a controlled substance must apply for a DEA registration. 21 U.S.C. 822(a)(1). Applications by persons seeking to grow marijuana to supply researchers are governed by 21 U.S.C. 823(a); *see generally* 76 FR 51403 (2011); 74 FR 2101 (2009). Under section 823(a), for DEA to grant a registration, two conditions must be satisfied: (1) The registration must be consistent with the public interest (based on the enumerated criteria listed in section 823(a)) and (2) the registration must be consistent with U.S. obligations under the Single Convention on Narcotic Drugs, 1961 (Single Convention). An applicant seeking registration under section 823(a) has "the burden of proving that the requirements for such registration pursuant to [this section] are satisfied." 21 CFR 1301.44(a). Although each application for registration that DEA receives will be evaluated individually based on its own merit, some general considerations warrant mention here.

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[1] There are two FDA-approved drugs that contain a synthetic form of dronabinol, which is one of the chemicals found in marijuana. These drugs are Marinol (which the FDA approved for the treatment of nausea and vomiting associated with cancer chemotherapy, and for the treatment of anorexia associated with weight loss in patients with AIDS) and Syndros (which was approved for the same indications as Marinol).

[2] Funding may actually be the most important factor in whether research with marijuana (or any other experimental drug) takes place. What appears to have been the greatest spike in marijuana research in the United States occurred shortly after the State of California enacted legislation in 1999 to fund such research. Specifically, in 1999, California enacted a law that established the "California Marijuana Research Program" to develop and conduct studies on the potential medical utility of marijuana. Cal. Health & Safety Code § 11362.9. The state legislature appropriated a total of $9 million for the marijuana research studies. Over the next five years, DEA received applications for registration in connection with at least 17 State-sponsored pre-clinical or clinical studies of marijuana (all of which DEA granted). 74 FR 2101, 2105 (2009). However, it appears that once the State stopped funding the research, the studies ended.

[3] An acceptable and broader definition of "cannabinoids" includes not only those chemicals unique to the cannabis plant but also their derivatives and transformation products.

First, while it is DEA's intention to increase the number of registered marijuana growers who will be supplying U.S. researchers, the CSA does not authorize DEA to register an unlimited number of manufacturers. As subsection 823(a)(1) provides, DEA is obligated to register only the number of bulk manufacturers of a given schedule I or II controlled substance that is necessary to "produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes." *See* 74 FR at 2127–2130 (discussing meaning of subsection 823(a)(1)). This provision is based on the long-established principle that having fewer registrants of a given controlled substances tends to decrease the likelihood of diversion.

Consistent with subsection 823(a)(1), DEA will evaluate each application it receives to determine whether adding such applicant to the list of registered growers is necessary to provide an adequate and uninterrupted supply of marijuana (including extracts and other derivatives thereof) to researchers in the United States.[4]

Second, as with any application submitted pursuant to section 823(a), in determining whether the proposed registration would be consistent with the public interest, among the factors to be considered are whether the applicant has previous experience handling controlled substances in a lawful manner and whether the applicant has engaged in illegal activity involving controlled substances. In this context, illegal activity includes any activity in violation of the CSA (regardless of whether such activity is permissible under State law) as well as activity in violation of State or local law. While past illegal conduct involving controlled substances does not automatically disqualify an applicant, it may weigh heavily against granting the registration.

Third, given the in-depth nature of the analysis that the CSA requires DEA to conduct in evaluating these applications, applicants should anticipate that, in addition to the information requested in the application itself, they will be asked to submit other information germane to the application in accordance with 21 CFR 1301.15. This will include, among other things, detailed information regarding an applicant's past experience in the manufacture of controlled substances. In addition, applicants will be asked to provide a written explanation of how they believe they would be able to augment the nation's supply of research-grade marijuana within the meaning of subsection 823(a)(1). Applicants may be asked to provide additional written support for their application and other information that DEA deems relevant in evaluating the application under section 823(a).

Treaty Considerations

As stated above, DEA may only issue a registration to grow marijuana to supply researchers if the registration is consistent with U.S. obligations under the Single Convention. Although this policy document will not list all of the applicable requirements of the Single Convention,[5] the following is a summary of some of the key considerations.

Under articles 23 and 28 of the Single Convention, a party (*i.e.,* a country that is a signatory to the treaty) that allows the cultivation of cannabis for lawful uses (*e.g.,* FDA-authorized clinical trials) must:

(a) Designate the areas in which, and the plots of land on which, cultivation of the cannabis plant for the purpose of producing cannabis shall be permitted;

(b) License cultivators authorized to cultivate cannabis;

(c) Specify through such licensing the extent of the land on which the cultivation is permitted;

(d) Purchase and take physical possession of all cannabis crops from all cultivators as soon as possible, but not later than four months after the end of the harvest; and

(e) Have the exclusive right of importing, exporting, wholesale trading and maintaining stocks of cannabis.

As DEA has stated in a prior publication, DEA carries out those functions of article 23, paragraph 2, that are encompassed by the DEA registration system (paragraphs (a) through (c) above), and NIDA carries out those functions relating to purchasing the marijuana and maintaining a monopoly over the wholesale distribution (paragraphs (d) and (e) above).[6] 76 FR at 51409.

As indicated, DEA's historical approach to ensuring compliance with the foregoing treaty requirements was to limit the registration of marijuana growers who supply researchers to those entities that operate under a contract with NIDA. Under this historical approach, the grower could be considered an extension of NIDA and thus all marijuana produced by the grower was effectively owned by NIDA, with NIDA controlling all distribution to researchers.

However, as further indicated, DEA has concluded, based on discussions with NIDA and FDA, that it would be beneficial for research to allow additional marijuana growers outside the NIDA-contract system, provided this could be accomplished in a manner consistent with the CSA and the treaty. Toward this end, DEA took into account the following statement contained in the official commentary to the Single Convention:

> Countries . . . which produce . . . cannabis . . . , [i]n so far as they permit private farmers to cultivate the plants . . . , cannot establish with sufficient exactitude the quantities harvested by individual producers. If they allowed the sale of the crops to private traders, they would not be in a position to ascertain with reasonable exactitude the amounts which enter their controlled trade. The effectiveness of their control régime would thus be considerably weakened. In fact, experience has shown that permitting licensed private traders to purchase the crops results in diversion of large quantities of drugs into illicit channels. . . . [T]he acquisition of the crops and the wholesale and international trade in these agricultural products cannot be entrusted to private traders, but must be undertaken by governmental authorities in the producing countries. Article 23 . . . and article 28 . . . therefore require a government monopoly of the wholesale and international trade in the agricultural product in question in the country which authorizes its production.

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[4] In making this determination, DEA will consult with NIH and FDA, as warranted.

[5] A detailed explanation of the relevant Single Convention requirements can be found in 74 FR at 2114–2118.

[6] In accordance with the CSA, DEA carries out functions that are indirectly related to those specified in article 23, paragraph 2(e). For example, DEA controls imports and exports of cannabis through the CSA registration and permitting system.

Given the foregoing considerations, DEA believes it would be consistent with the purposes of articles 23 and 28 of the Single Convention for DEA to register marijuana growers outside of the NIDA-contract system to supply researchers, *provided the growers agree that they may only distribute marijuana with prior, written approval from DEA.* In other words, in lieu of requiring the growers to operate under a contract with NIDA, a registered grower will be permitted to operate independently, provided the grower agrees (through a written memorandum of agreement with DEA) that it will only distribute marijuana with prior, written approval from DEA. DEA believes this new approach will succeed in avoiding one of the scenarios the treaty is designed to prevent: Private parties trading in marijuana outside the supervision or direction of the federal government.

Also, consistent with the purposes and structure of the CSA, persons who become registered to grow marijuana to supply researchers will only be authorized to supply DEA-registered researchers whose protocols have been determined by the Department of Health and Human Services (HHS) to be scientifically meritorious. *See* 21 U.S.C. 823(f). In 2015, HHS announced the details of its current policy for evaluating the merits of research protocols involving marijuana. 80 FR 35960 (2015).

Finally, potential applicants should note that any entity granted a registration to manufacture marijuana to supply researchers will be subject to all applicable requirements of the CSA and DEA regulations, including those relating to quotas, record keeping, order forms, security, and diversion control.

How To Apply for a Registration

Persons interested in applying for a registration to become a bulk manufacturer of marijuana to supply legitimate researchers can find instructions and the application form by going to the DEA Office of Diversion Control Web site registration page at *www.deadiversion.usdoj.gov/drugreg/index.html#regapps.* Applicants will need to submit Form 225.

Note Regarding the Nature of This Document

This document is a general statement of DEA policy. While this document reflects how DEA intends to implement the relevant statutory and regulatory provisions, it does not establish a rule that is binding on any member of the public. Any person who applies for a registration to grow marijuana (as with any other applicant for registration under the CSA) is entitled to due process in the consideration of the application by the Agency. To ensure such due process, the CSA provides that, before taking action to deny an application for registration, DEA must serve upon the applicant an order to show cause why the application should not be denied, which shall provide the applicant with an opportunity to request a hearing on the application in accordance with the Administrative Procedure Act. 21 U.S.C. 824(c).

Dated: July 25, 2016.

Chuck Rosenberg,

Acting Administrator.

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Part V

Department of Transportation

Federal Railroad Administration

49 CFR Part 270
System Safety Program; Final Rule

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

49 CFR Part 270

[Docket No. FRA–2011–0060, Notice No. 3]

RIN 2130–AC31

System Safety Program

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: FRA is issuing this final rule to mandate that commuter and intercity passenger railroads develop and implement a system safety program (SSP) to improve the safety of their operations. A SSP is a structured program with proactive processes and procedures, developed and implemented by commuter and intercity passenger railroads to identify and mitigate or eliminate hazards and the resulting risks on each railroad's system. A railroad has the flexibility to tailor a SSP to its specific operations. A SSP will be implemented after receiving approval by FRA of a submitted SSP plan. FRA will audit a railroad's compliance with its SSP.

DATES: This final rule is effective October 11, 2016. Petitions for reconsideration must be received on or before October 3, 2016. Comments in response to petitions for reconsideration must be received on or before November 15, 2016.

ADDRESSES: *Petitions for reconsideration and comments on petitions for reconsideration:* Any petitions for reconsideration or comments on petitions for reconsideration related to this Docket No. FRA–2011–0060, Notice No. 3, may be submitted by any of the following methods:

- *Web site:* The Federal eRulemaking Portal, *www.regulations.gov.* Follow the Web site's online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., Room W12–140, Washington, DC 20590.
- *Hand Delivery:* Docket Management Facility, Room W12–140 on the ground level of the West Building, U.S. Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Instructions: All submissions must include the agency name and docket number or Regulatory Identification Number (RIN) for this rulemaking (2130–AC31). Note that all petitions and comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading in the **SUPPLEMENTARY INFORMATION** section of this document for Privacy Act information related to any submitted petitions, comments or materials.

Docket: For access to the docket to read background documents, petitions for reconsideration, or comments received, go to *http://www.regulations.gov* at any time or visit the Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., Room W12–140, on the Ground level of the West Building, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

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I. Executive Summary

A. Purpose of Rulemaking

This rule requires commuter and intercity passenger railroads (passenger railroads) to develop and implement a system safety program (SSP). A SSP is a structured program with proactive processes and procedures, developed and implemented by passenger railroads. These processes and procedures will identify then mitigate or eliminate hazards and the resulting risks on the railroad's system. A SSP encourages a railroad and its employees to work together to proactively identify hazards and to jointly determine what, if any, action to take to mitigate or eliminate the resulting risks. The rule provides each railroad with a certain amount of flexibility to tailor its SSP to its specific operations. The SSP rule is part of FRA's efforts to continuously improve rail safety and to satisfy the statutory mandate in the Rail Safety Improvement Act of 2008 (RSIA), secs. 103 and 109, Public Law 110–432, Division A, 122 Stat. 4848 *et seq.,* codified at 49 U.S.C. 20156, 20118, and 20119.

On September 7, 2012, FRA published a notice of proposed rulemaking (NPRM) to address the following mandates for commuter and intercity passenger railroads. 77 FR 55372, Sept. 7, 2012. Section 103 (49 U.S.C. 20156) of RSIA enacted a statutory provision directing the Secretary of Transportation (Secretary) to issue a regulation requiring certain railroads, including passenger railroads, to develop, submit to the Secretary for review and approval, and implement a railroad safety risk reduction program. FRA is establishing separate safety risk reduction program rules for passenger railroads (SSP) and certain freight railroads (Risk Reduction Program) to account for the significant differences between passenger and freight operations. Section 109 (codified at 49 U.S.C. 20118 and 20119) of RSIA enacted a statutory provision authorizing the Secretary to issue a regulation protecting from discovery and admissibility into evidence in litigation documents generated for the purpose of developing, implementing, or evaluating a safety risk reduction program. This final rule implements these statutory mandates with respect to the system safety program covered by part 270. The Secretary has delegated such statutory responsibilities to the Administrator of FRA. *See* 49 CFR 1.89.

B. Summary of Major Provisions

A SSP is implemented by a written SSP plan. The SSP regulation sets forth various elements that a railroad's SSP plan is required to contain to properly implement a SSP. The main components of a SSP are the risk-based hazard management program and risk-based hazard analysis. A properly implemented risk-based hazard management program and risk-based hazard analysis will identify the hazards and resulting risks on the railroad's system, require railroads to develop methods to mitigate or eliminate, if practicable, these hazards and risks, and set forth a plan to implement these methods. As part of its risk-based hazard analysis, a railroad will consider various technologies that may mitigate or eliminate the identified hazards and risks.

As part of its SSP plan, a railroad will also be required to describe the various procedures, processes, and programs it has in place that support the goals of the SSP. These procedures, processes, and programs include, but are not limited to, the following: A maintenance, inspection, and repair program; rules compliance and procedures review(s); SSP employee/contractor training; and a public safety outreach program. Since railroads should already have most of these procedures, processes, and programs in place, railroads will most likely only have to identify and describe such procedures, processes, and programs to comply with the regulation.

A SSP can be successful only if a railroad engages in a robust assessment of the hazards and resulting risks on its system. However, a railroad may be reluctant to reveal such hazards and risks if there is the possibility that such information may be used against it in a court proceeding for damages. Congress directed FRA to conduct a study to determine if it was in the public interest to withhold certain information, including the railroad's assessment of its safety risks and its statement of mitigation measures, from discovery and admission into evidence in proceedings for damages involving personal injury and wrongful death. *See* 49 U.S.C. 20119. Furthermore, Congress authorized FRA, by delegation from the Secretary, to prescribe a rule, subject to notice and comment, to address the results of the study. *See* 49 U.S.C. 20119(b). FRA contracted to have the study performed and the SSP NPRM addressed the study's results and set forth proposed protections for certain information from discovery, admission into evidence, or use for other purposes in a proceeding for damages. 77 FR 55406, Sept. 7, 2012.

To minimize the information protected, information that is generated *solely for the purpose of developing, implementing, or evaluating a SSP* is protected from (1) discovery, or admissibility into evidence, or use for other purposes in a proceeding for damages involving personal injury, wrongful death, or property damage, and (2) State discovery rules and sunshine laws which could be used to require the disclosure of such information. Information that is compiled or collected for a purpose unrelated to the railroad's SSP is not protected. Under section 109 of RSIA, the information protection provision is not effective until one year after its publication.

In addition to protection from discovery, 49 U.S.C. 20118 specifies that certain risk reduction records obtained by the Secretary also are exempt from the public disclosure requirements of the Freedom of Information Act (FOIA). Records protected under this exemption may only be disclosed if disclosure is necessary to enforce or carry out any Federal law, or disclosure is necessary when a record is comprised of facts otherwise available to the public and FRA has determined that disclosure would be consistent with the confidentiality needed for SSPs. FRA therefore believes that railroad risk reduction records in FRA's possession would generally be exempted from mandatory disclosure under FOIA. Unless one of the two exceptions provided by section 20118 would apply, FRA would withhold disclosing any such records in response to a FOIA request. *See* 5 U.S.C. 552(b)(3) and 49 CFR 7.13(c)(3).

A SSP will affect almost all facets of a railroad's operations. To ensure all employees directly affected by a SSP have an opportunity to provide input on the development, implementation, and evaluation of a railroad's SSP, a railroad must consult in good faith and use best efforts to reach agreement with all directly affected employees on the contents of the SSP plan and amendments to the plan. In an appendix, the rule provides guidance regarding what constitutes "good faith" and "best efforts."

This rule will become effective 60 days after the publication of the final rule except the protection of certain information discussed above will not become effective until one year after the final rule is published. A railroad is required to submit its SSP plan to FRA for review not more than 180 days after the applicability date of the discovery protections, *i.e.,* 485 days after the effective date of the final rule, or not less than 90 days before commencing operations, whichever is later. Within 90 days of receipt of the SSP plan, FRA will review the plan and determine if it meets all the requirements in the regulation. If, during the review, FRA determines that the railroad's SSP plan does not comply with the requirements, FRA will notify the railroad of the specific points in which the plan is deficient. The railroad will then have 90 days to correct these deficient points and resubmit the plan to FRA. Whenever a railroad amends its SSP, it is required to submit an amended SSP plan to FRA for approval and provide a cover letter describing the amendments. A similar approval process and timeline would apply whenever a railroad amends its SSP.

FRA will work with the railroad and other necessary stakeholders throughout the development of its SSP to help the railroad properly tailor the program to its specific operation.

C. Summary of the Costs and Benefits

Most of the passenger railroads affected by this rulemaking already participate in the American Public Transportation Association (APTA) system safety program and are currently participating in the APTA audit program. Railroads that are still negotiating contracts or not participating directly with APTA, have developed, or are in the process of developing an APTA system safety program. Since the majority of intercity passenger or commuter railroads already have APTA system safety programs, there will not be a significant cost for these railroads to implement the regulatory requirements in this final rule. Thus, the economic impact of the final rule is generally incremental in nature for documentation of existing information and inclusion of certain elements not already addressed by railroads in their existing programs.

FRA estimated costs in the following areas: Documenting the SSP plan and the safety certification process; SSP training; preparing for and providing information in response to external audits; providing mitigation method information to FRA; preparing technology analysis results and providing them to FRA; providing an annual assessment of SSP performance and improvement plans; consulting with directly affected employees and preparing consultation statements, amending SSP plans; retaining records; and conducting internal SSP assessments.

FRA also addressed the use and costs of data protection, which is an important element of this rule. While the rule may protect from discovery some information that in the absence of the rule would not be protected, FRA concludes that the benefits of the protections justify the costs. Without the protections, railroads' risk-based hazard analysis and mitigations may be less robust, which may lead to a less safe environment than with the protections in place. No specific or net incremental costs are incurred by the protections (record keeping and reporting paperwork costs are accounted for in the rule). The information protections are important to ensure the effectiveness of a SSP at almost no additional regulatory cost to the railroad. This means that the information protections provide an incentive to the railroad to be forthright about identified risks, without concern the information may be used in litigation against them.

Total estimated twenty-year costs associated with implementation of the final rule, for existing passenger railroads, range from $2.0 million (discounted at 7%) to $2.9 million (discounted at 3%).

FRA believes that there will be new, startup passenger railroads that will be formed during the twenty-year analysis period. FRA is aware of two passenger railroads that intend to begin operations in the near future. FRA assumed that one of these railroads would begin developing its SSP in Year 2, and that the other would begin developing its SSP in Year 3. FRA further assumed that one additional passenger railroad would be formed and begin developing its SSP every other year after that, in Years 5, 7, 9, 11, 13, 15, 17 and 19. Total estimated twenty-year costs associated with implementation of the final rule, for startup passenger railroads, range from $297 thousand (discounted at 7%) to $485 thousand (discounted at 3%).

Total estimated twenty-year costs associated with implementation of the final rule, for existing passenger railroads and startup passenger railroads, range from $2.3 million (discounted at 7%) to $3.4 million (discounted at 3%).

The estimated costs for existing and startup passenger railroads to implement this rule do not include costs of mitigations that railroads may implement to address hazards, as the cost of hazard mitigation will vary greatly depending on what hazard is being eliminated or mitigated. FRA expects that railroads will implement the most cost-effective mitigations to eliminate or mitigate hazards.

Properly implemented SSPs may be successful in optimizing the returns on railroad safety investments. Railroads can use them to proactively identify potential hazards and resulting risks at an early stage, thus minimizing associated casualties and property damage or avoiding them altogether. Railroads can also use them to identify a wide array of potential safety issues and solutions, which in turn may allow them to simultaneously evaluate various alternatives for improving overall safety with resources available. This results in more cost effective investments. In addition, system safety planning may help railroads maintain safety gains over time. Without a SSP plan to guide them, railroads could adopt countermeasures to safety problems that become less effective over time as the focus shifts to other issues. With SSP plans, those safety gains are likely to continue for longer time periods. SSP plans can also be instrumental in reducing casualties resulting from hazards that are not well addressed through conventional safety programs.

During the course of daily operations, hazards are routinely discovered. Railroads must decide which hazards to address and how, with the limited resources available for this purpose. Without a SSP plan in place, the decision process might become arbitrary. In the absence of the information protections provided by the final rule, railroads might also be reluctant to keep detailed records of known hazards. With a SSP plan in place, railroads may be better able to identify and implement the most cost-effective measures to reduce accidents and incidents and resulting casualties.

The SSP NPRM Regulatory Impact Analysis (RIA) was performed on a breakeven basis. The approach has been modified for the final rule due to the lack of empirical evidence currently available to estimate all relevant regulatory costs, namely those from risk analysis and risk mitigation. These costs are not reasonably predictable until the data protections are in place and each railroad produces and implements their SSP plans assessing their hazards and risk levels. The pool of potential safety benefits is large as evidenced by the totality of accidents and incidents experienced on passenger railroads that this final rule could impact. FRA expects that railroads can achieve sufficient safety benefits to justify quantified and unquantified costs.

SSPs under the APTA program are currently voluntary. This rule focuses on a robust risk-based hazard analysis and mitigation, and the oversight required to achieve full compliance. Passenger railroads must demonstrate a robust SSP and the means to implement the SSP and assure compliance. Railroad management and employees will be accountable to achieve the safety goals in their SSPs, but there will also be FRA oversight to monitor and demand corrective actions if and when necessary.

As documented in the RIA, FRA expects that regulatory costs under the SSP final rule will be modest and only incremental in relation to the railroads' non-regulatory costs because the rule provides information to the industry on what FRA's expectations are for a robust SSP. Railroads should be able to assemble a SSP plan to satisfy the rule by packaging what they currently have under the APTA program that complies with the SSP rule's provisions, along with (1) greater emphasis on eliminating or reducing hazards and the resulting risks, (2) rigorous analysis process, and (3) commitment to achieve the railroad's safety goal through setting priorities of its risk reduction efforts of mitigation. The SSP final rule would also address any gaps in those plans that do not meet the requirements of this rule. The few railroads that are not under the APTA program have their own SSPs or are developing such with FRA's assistance. For instance, when a hazard analysis is performed, this rule requires the railroad to demonstrate the processes and procedures it used to carry-out the analysis and mitigation. This means that, for the most part, FRA would only require actions to address gaps in the SSP plans, such as providing a clear or more robust description of the methods and processes they will use. These actions are expected to maintain and improve the economic benefit that can be achieved through the use of a robust SSP. However, it is difficult to provide a precise cap on the regulatory costs and benefits because the type and level of hazards and corresponding risk are not known, which is why FRA could not estimate benefits quantitatively.

A benefit (not quantified) of this rule is that it may promote more cost-effective investment of railroad resources. However, FRA does not know to what extent. Therefore, FRA focused on the passenger railroad accidents and incidents this rule will impact. FRA analyzed passenger operation-related accident costs—the costs of accidents this final rule could affect. Between 2001 and 2010, on average, passenger railroads had 3,724 accidents, resulting in 208 fatalities, 3,340 other casualties, and $20.6 million in damage to railroad track and equipment each year. Total quantified twenty-year accident costs total between $33 billion (discounted at 7%) and $51 billion (discounted at 3%). Of course, these accidents also resulted in damage to other property, delays to both railroads and highway users, emergency response and clean-up costs, and other costs not quantified in this analysis. In conclusion, FRA is confident that the accident reduction benefits should justify the $2.3 million (discounted at 7%) to $3.4 million (discounted at 3%) implementation cost over the first twenty years of the final rule.

TABLE 1—TOTAL COSTS (OVER 20-YEAR PERIOD) AND ANNUALIZED

	Current dollar value	Discounted value 7 percent	Discounted value 3 percent
Total	$4,743,039	$2,327,224	$3,412,651
Annualized	237,152	219,674	229,384

This rule will certainly have benefits incremental to the APTA program. However, FRA could not estimate the benefits of the final rule as SSPs are mostly an organizational structure and program to manage safety through hazard analysis and mitigation. FRA cannot accurately estimate the rule's incremental safety benefits because FRA cannot reliably predict the specific risks each railroad will identify or the specific actions they will take to mitigate such risks relative to the APTA program.

II. Background and History

A. System Safety Program—Generally

On September 7, 2012, FRA published an NPRM proposing to require commuter and intercity passenger railroads to develop and implement a SSP to improve the safety of their operations. 77 FR 55372, Sept. 7, 2012. The NPRM was proposed as part of FRA's efforts to continuously improve rail safety and to satisfy the statutory mandates in 49 U.S.C. 20156, 20118, and 20119.

Railroads operate in a dynamic, fast-paced environment that at one time posed extreme safety risks. Through concerted efforts by railroads, labor organizations, the U.S. DOT, and many other entities, railroad safety has vastly improved. Even though FRA has issued safety regulations and guidance that address many aspects of railroad operations, gaps in safety exist, and hazards and risks may arise from these gaps. FRA believes that railroads are in an excellent position to identify many of these gaps and take the necessary action to mitigate or eliminate the arising hazards and resulting risks. Rather than prescribing the specific actions the railroads need to take, FRA believes it will be more effective to allow the railroads to use their knowledge of their unique operating environment to identify the gaps and determine the best methods to mitigate or eliminate the hazards and resulting risks. A SSP provides a railroad with the tools to systematically and continuously evaluate its system to identify hazards and the resulting risks gaps in safety and to mitigate or eliminate these hazards and risks.

There are many programs that are similar to a SSP. Most notably, the Federal Aviation Administration (FAA) has published a final rule requiring each certificate holder operating under 14 CFR part 121 to develop and implement a safety management system (SMS). 80 FR 1308, Jan. 8, 2015. An SMS is a comprehensive, process-oriented approach to managing safety throughout the organization. An SMS includes an organization-wide safety policy; formal methods for identifying hazards, controlling, and continually assessing risk; and promotion of safety culture. Under FAA's final rule an SMS has four components: Safety Policy, Safety Risk Management, Safety Assurance, and Safety Promotion. *Id.* Similar components can also be found in this SSP rule.

The U.S. Department of Defense (DoD) has also set forth guidelines for a System Safety Program. In July 1969, DoD published "System Safety Program Plan Requirements" (MIL–STD–882). MIL–STD–882 is DoD's standard practice for system safety, with the most recent version, MIL–STD–882E, published on May 11, 2012. DoD, *MIL–STD–882E, Department of Defense Standard Practice System Safety.* MIL–STD–882 is used by many industries in the U.S. and internationally and certainly could be of use to a railroad when trying to determine which methods to use to comply with the SSP rule. In fact, MIL–STD–882 is cited in FRA's safety regulations for railroad passenger equipment, 49 CFR part 238, as an example of a formal safety methodology to use in complying with certain analysis requirements in that rule. *See* 49 CFR 238.103 and 238.603.

B. System Safety Program Overview and Related Actions

i. System Safety at FRA

As discussed in the NPRM, system safety is not a new concept to FRA. *See* 77 FR 55374. This final rule responds to the statutory mandates set forth in RSIA and is based on lessons learned from past experience with various elements of system safety, as well as recommendations from the Railroad Safety Advisory Committee (RSAC).

ii. Federal Transit Administration's Part 659 and MAP–21 Program

As discussed in the NPRM, the Federal Transit Administration has set forth a regulation that covers State-conducted oversight of the safety and security of rail fixed guideway systems that were not regulated by FRA. *See* 77 FR 55375, Sept. 7, 2012; 49 CFR part 659. On March 16, 2016, FTA published the State Safety Oversight (SSO) final rule. 81 FR 14230, Mar. 16, 2016. The SSO rule replaces part 659 and implements certain provisions of the Moving Ahead for Progress in the 21st Century Act, Public Law 112–141 (2012). Many of the same concepts from part 659 are incorporated in the SSP final rule.

MAP–21 made a number of fundamental changes to the statutes that authorize FTA programs at 49 U.S.C. ch. 53. On October 3, 2013, FTA published an advance notice of proposed rulemaking (ANPRM) seeking comment on the implementation of these changes. *See* 78 FR 61251, Oct. 3, 2013. The ANPRM sought comment on several provisions within the Public Transportation Safety Program (National Safety Program) authorized at 49 U.S.C. 5329, and the transit asset management (National TAM System) requirements authorized at 49 U.S.C. 5326. *Id.* Specifically, FTA sought comment on its initial interpretations, proposals, and questions regarding: (1) The requirements of the National Safety Program relating to the National Public Transportation Safety Plan, the Public Transportation Agency Safety Plan, and the Public Transportation Safety Certification Training Program; (2) the requirements of the National TAM System, including four proposed options under consideration for defining and measuring state of good repair; and (3) the relationship between safety, transit asset management, and state of good repair. *Id.* at 61252. FTA also sought comment on its intent to propose adoption of the SMS[1] approach as the method to develop and implement the National Safety Program. *Id.* While many of the requirements of the National Safety Program and the National TAM System apply equally to all modes of public transportation, FTA intends to focus, initially, on rail transit systems' implementation of and compliance with these requirements. *Id.* at 61251.

In the ANPRM, FTA made it clear that if another Federal agency (*e.g.,* FRA) regulates the safety of a particular mode of transportation, FTA, as part of the rulemaking pursuant to MAP–21, does not intend to set forth duplicative, inconsistent, or conflicting regulations. 78 FR 61251, Oct. 3, 2013. FTA specifically highlighted that it does not intend to promulgate safety regulations that will apply to either commuter rail systems that are regulated by FRA. *Id.* Further, FTA's regulatory jurisdiction is explicitly limited by two statutory provisions. *Id.* at 61253. First, FTA is prohibited from promulgating safety performance standards for rolling stock that is already regulated by another Federal agency, *e.g.,* FRA. *See* 49 U.S.C. 5329(b)(2)(C)(i). Second, the requirements of the State Safety Oversight Program will not apply to rail transit systems that are subject to regulation by FRA. *See* 49 U.S.C. 5329(e)(1) and (e)(2).

On February 5, 2016, FTA published an NPRM proposing requirements for the Public Transportation Agency Safety Plan. 81 FR 6344. The NPRM proposed "requirements for the adoption of Safety Management Systems (SMS) principles and methods; the development, certification, and update of Public Transportation Agency Safety Plans; and the coordination of Public Transportation Agency Safety Plan elements with other FTA programs and proposed rules, as specified in 49 U.S.C. 5329." *Id.* at 6344–45. The NPRM reaffirms FTA's intent not to promulgate safety regulations that would apply to commuter rail systems that are regulated by the FRA. *Id.* at 6345, 6346, 6351, 6353, 6361, and 6369. FTA clarifies that, primarily, due to the information protections set forth in this FRA SSP rule, a public transportation provider cannot use its SSP for other modes of transportation aside from a commuter rail operation that falls under this SSP rule. *Id.* at 6351.

Since FRA is publishing the SSP final rule after FTA published the NPRM for Public Transportation Agency Safety Plans (the FTA Agency Safety Plan NPRM), but before the FTA Agency Safety Plan final rule, railroads and other interested stakeholders will have the opportunity to compare the SSP final rule with the FTA Agency Safety Plan NPRM.

iii. Risk Reduction Program Rulemaking

FRA is currently developing, with the assistance of the RSAC, a separate risk reduction rule, referred to as the risk reduction program (RRP), that would implement the requirements of sections 20156, 20118, and 20119 for Class I freight railroads and railroads with inadequate safety performance. The RRP NPRM was published in the **Federal Register** on February 27, 2015. 80 FR 10949. The RRP rulemaking is discussed *infra* in the "Statutory Background" section.

iv. FRA's Confidential Close Call Reporting System and Clear Signal for Action Program

FRA also has established two voluntary, independent programs that exemplify the philosophy of risk reduction: The Confidential Close Call Reporting System (C3RS) and the Clear Signal for Action (CSA) program.[2] FRA has developed these programs in the belief that, in addition to process and technology innovations, human factors-based solutions can make a significant contribution to improving safety in the railroad industry.

The C3RS and CSA program embody many of the concepts and principles found in a SSP: Proactive identification of hazards and risks, analysis of those hazards and risks, and implementation of appropriate action to eliminate or mitigate the hazards and risks. While FRA does not require any railroad to implement a C3RS or CSA program as part of their SSP, FRA does believe that these types of programs would prove useful in the development of a SSP and encourages railroads to include such programs as part of their SSP.

C. FRA's Railroad Safety Advisory Committee

The SSP rule was developed with the assistance of the RSAC.[3] This rule incorporates the majority of RSAC's recommendations. FRA decided not to incorporate certain recommendations because they were unnecessary or duplicative and their exclusion would not have a substantive effect on the rule. The rule also contains elements that were not part of RSAC's recommendations. The majority of these elements are added to provide clarity and to conform to **Federal Register** formatting requirements. However, FRA notes the areas in which the exclusion of the RSAC recommendations or the inclusion of elements not part of the RSAC recommendations do have a substantive effect on the rule and will provide an explanation for doing so.

III. Statutory Background

A. Rail Safety Improvement Act of 2008

In section 103 of the RSIA, Congress enacted a statutory provision directing the Secretary to issue a regulation requiring certain railroads to develop, submit to the Secretary for review and approval, and implement a railroad safety risk reduction program. This statutory mandate is codified at 49 U.S.C. 20156 (section 20156). The Secretary has delegated this statutory responsibility to the FRA Administrator. *See* 49 CFR 1.89, 77 FR 49965, 49984, Aug. 17, 2012; *see also* 49 U.S.C. 103(g). The railroads required to be subject to such a regulation include the following:

(1) Class 1 railroads;

(2) Railroad carriers with inadequate safety performance, as determined by the Secretary; and

(3) Railroad carriers that provide intercity rail passenger or commuter rail passenger transportation (passenger railroads).

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[1] As discussed previously, FAA has published a final rule requiring each certificate holder operating under 14 CFR part 121 to develop and implement an SMS. *See* 80 FR 1308.

[2] The history and structure of C3RS and CSA program were discussed extensively in the SSP NPRM. 77 FR 55375–76.

[3] The history, structure, and SSP-related proceedings were discussed extensively in the SSP NPRM. 77 FR 55376–78.

The SSP rule implements sections 20156, 20118, and 20119 as they apply to railroad carriers that provide intercity rail passenger or commuter rail passenger transportation (passenger railroads). The SSP rule is a risk reduction program in that it requires a passenger railroad to assess and manage risk and to develop proactive hazard management methods to promote safety improvement. The rule contains provisions that, while not explicitly required by the statutory safety risk reduction program mandate, are necessary to properly implement the mandate and are consistent with the intent behind the mandate. Further, as mentioned previously, many of the elements in the rule are modeled after the APTA System Safety Manual; therefore, the majority of railroads will have already implemented those elements. The rule also implements section 20119, which addresses the protection of information in railroad safety risk analyses and will be discussed further in the rule.

B. Related Risk Reduction Rulemaking

As discussed, *supra,* the RRP NPRM proposes implementing the requirements of sections 20156, 20118, and 20119 for Class I freight railroads and railroads with inadequate safety performance. To avoid duplicative requirements, as proposed, the RRP rule would not apply to any passenger railroad already required to comply with the SSP rule. Establishing separate safety risk reduction rules for passenger railroads and Class I freight railroads will allow those rules to account for the significant differences between passenger and freight operations. For example, passenger operations generate risks uniquely associated with the passengers that utilize their services. The SSP rule can be tailored specifically to these types of risks, which are not independently generated by freight railroads. Further, freight railroads may generate risks uniquely associated with the transportation of hazardous materials and the proposed RRP rule can be specifically tailored to these types of risks, which are not independently generated by passenger railroads.

Some overlap may exist between certain components of the SSP and RRP rules. Most significantly, the SSP and RRP final rules most likely will contain similar provisions implementing the consultation requirements of section 20156(g) and responding to the information protection study section 20119(a) mandated. There was significant discussion during the SSP and RRP RSAC processes on how to implement these statutory mandates. FRA worked with the General Passenger Safety Task Force's System Safety Task Group and the RRP Working Group to receive input regarding how information protection and the consultation process should be addressed, with the understanding that the same language would be included in both the SSP and RRP NPRMs for review and comment. Based on the comments received in response to the SSP NPRM, FRA has revised the consultation process requirement and the information protections. These revisions are discussed further in the discussion of comments section.

C. System Safety Information Protection

Section 20119(b) authorizes FRA to issue a rule protecting risk analysis information generated by railroads. These provisions would apply to information generated by passenger railroads pursuant to a SSP.

i. Exemption From Freedom of Information Act Disclosure

In section 20118, Congress determined that for risk reduction programs to be effective, the risk analyses must be shielded from production in response to FOIA requests. FOIA is a Federal statute establishing certain requirements for the public disclosure of records held by Federal agencies. *See* 5 U.S.C. 552. Formal rules for making FOIA requests to DOT agencies are set forth in 49 CFR part 7. Generally, FOIA requires a Federal agency to make most records available upon request, unless a record is protected from mandatory disclosure by one of nine exemptions. One of those exemptions, known as Exemption 3, applies to records that are specifically exempted from disclosure by statute, if the statute requires that matters be withheld from the public in such a manner as to leave no discretion on the issue or establishes particular criteria for withholding or refers to particular types of matters to be withheld. *See* 5 U.S.C. 552(b)(3) and 49 CFR 7.13(c)(3).

Section 20118(a) specifically provides that a record obtained by FRA pursuant to a provision, regulation, or order related to a risk reduction program or pilot program is exempt from disclosure under FOIA. The term "record" includes, but is not limited to, "a railroad carrier's analysis of its safety risks and its statement of the mitigation measures it has identified with which to address those risks." *Id.* This FOIA exemption also applies to records made available to FRA for inspection or copying pursuant to a risk reduction program or pilot program. Section 20118(c) also gives FRA the discretion to prohibit the public disclosure of risk analyses or risk mitigation analyses obtained under other FRA regulations if FRA determines that the prohibition of public disclosure is necessary to promote public safety.

FRA believes that section 20118 qualifies as an Exemption 3 statute under FOIA.[4] FRA therefore believes that SSP records in its possession are exempted from mandatory disclosure under FOIA, unless one of two exceptions provided by the statute would apply. *See* 49 U.S.C. 20118(a)–(b). The first exception permits disclosure when it is necessary to enforce or carry out any Federal law. The second exception permits disclosure when a record is comprised of facts otherwise available to the public and when FRA, in its discretion, has determined that disclosure would be consistent with the confidentiality needed for a risk reduction program or pilot program.

ii. Discovery and Other Use of Risk Analysis Information in Litigation

1. The Statutory Mandate

The RSIA also addressed the disclosure and use of risk analysis information in litigation. Section 20119(a), one of the statutory provisions enacted by the RSIA, directed FRA to conduct a study to determine whether it was in the public interest to withhold from discovery or admission into evidence in a Federal or State court proceeding for damages involving personal injury or wrongful death against a carrier any information (including a railroad's analysis of its safety risks and its statement of the mitigation measures with which it will address those risks) compiled or collected for the purpose of evaluating, planning, or implementing a risk reduction program. In conducting this study, section 20119(a) required FRA to solicit input from railroads, railroad non-profit employee labor organizations, railroad accident victims and their families, and the general public. *See id.* Section 20119(b) also states that upon completion of the study, if in the public interest, FRA may prescribe a rule to address the results of the study (*i.e.,* a rule to protect risk analysis information from disclosure during litigation). Section 20119(b) prohibits any such rule from becoming effective until one year after its adoption.

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[4] In 2009, Congress amended 5 U.S.C. 552(b)(3) to require Exemption 3 statutes to specifically cite to section 552(b)(3). *See* OPEN FOIA Act of 2009, Public Law 111–83, 123 Stat. 2142, 2184 (Oct. 28, 2009). Because this requirement applies only to statutes enacted after October 29, 2009, however, it does not apply to section 20118, which was enacted in October of 2008.

2. The Study and Its Conclusions

FRA contracted with a law firm, Baker Botts L.L.P., to conduct the study on FRA's behalf. Various documents related to the study are available for review in public docket number FRA–2011–0025, which can be accessed online at *www.regulations.gov.* As a first step, the contracted law firm prepared a comprehensive report identifying and evaluating other Federal safety programs that protect risk reduction information from use in litigation. *See Report on Federal Safety Programs and Legal Protections for Safety-Related Information,* FRA, docket no. FRA–2011–0025–0002, April 14, 2011. Next, as required by section 20119(a), FRA published a **Federal Register** notice seeking public comment on the issue of whether it would be in the public interest to protect certain railroad risk reduction information from use in litigation. *See* 76 FR 26682, May 9, 2011. Comments received in response to this notice may be viewed in the public docket.

On October 21, 2011, the contracted law firm produced a final report on the study. *See Study of Existing Legal Protections for Safety-Related Information and Analysis of Considerations For and Against Protecting Railroad Safety Risk Reduction Program Information* (final report), FRA, docket no. FRA–2011–0025–0031, Oct. 21, 2011. The final report contained analyses of other Federal programs that protect similar risk reduction data, the public comments submitted to the docket, and whether it would be in the public interest, including the interests of public safety and the legal rights of persons injured in railroad accidents, to protect railroad risk reduction information from disclosure during litigation.

The final report determined that substantial support exists for the conclusion that a rule that protects "railroad safety risk information from use in civil litigation involving claims for personal injuries or wrongful death would serve the broader public interest." *Study of Existing Legal Protections* at 63. The final report highlighted the fact that, in the past with similar programs, Congress has deemed that it is in the public's interest to place statutory limitations on the disclosure or use of certain information for use by the Federal government. *Id.* The safety risk reduction programs RSIA mandated, according to the final report, involve public interest considerations similar to the ones Congress has protected through statutory limitations and these limitations have been upheld by courts. Many of the comments to the final report agree that limiting the use on information collected pursuant to a safety risk reduction program mandated by RSIA in discovery or litigation would serve the broad public interest by encouraging and facilitating the timely and complete disclosure of safety-related information to FRA. Further, the final report underscored FRA's statutory duty to protect the broader public interest in ensuring rail safety and that this public interest outweighs the individual interests of future litigants who may bring damage claims against railroads. Therefore, the final report concluded "after balancing all of the considerations that bear upon the public interest . . . the balance weighs in favor of adopting rules prohibiting the admissibility or discovery of information compiled or collected for FRA railroad safety risk reduction programs in a civil action where a plaintiff seeks damages for personal injury or wrongful death." *Id.* at 64.

In response to the final report, the SSP NPRM proposed in § 270.105 to protect any information compiled or collected solely for the purpose of developing, implementing or evaluating a RRP from discovery, admission into evidence, or consideration for other purposes in a Federal or State court proceeding for damages involving personal injury, wrongful death, and property damage. The information protected includes a railroad's identification of its safety hazards, analysis of its safety risks, and its statement of the mitigation measures with which it would address those risks and could be in the following forms or other forms: plans, reports, documents, surveys, schedules, lists, or data. FRA received multiple comments in response to the proposed information protections and made revisions based on these comments. These revisions are discussed further in the discussion of comments section and the corresponding section-by-section analysis.

D. Consultation Requirements

Section 20156(g)(1), states that a railroad required to establish a safety risk reduction program must "consult with, employ good faith and use its best efforts to reach agreement with, all of its directly affected employees, including any non-profit employee labor organization representing a class or craft of directly affected employees of the railroad carrier, on the contents of the safety risk reduction program." Section 20156(g)(2) further provides that if a "railroad carrier and its directly affected employees, including any nonprofit employee labor organization representing a class or craft of directly affected employees of the railroad carrier, cannot reach consensus on the proposed contents of the plan, then directly affected employees and such organizations may file a statement with the Secretary explaining their views on the plan on which consensus was not reached." FRA must consider these views during review and approval of a railroad's SSP plan.

In the NPRM, FRA proposed to implement this mandate by requiring each railroad required to establish a SSP to consult with its directly affected employees (using good faith and best efforts) on the contents of its SSP plan. A railroad is required to include a consultation statement in its submitted plan describing how it consulted with its employees. If a railroad and its employees were not able to reach consensus, directly affected employees could file a statement with FRA describing their views on the plan.

As with the information protection provisions, FRA anticipates the RRP rule will have essentially identical provisions regarding the consultation requirements since there was significant discussion during the SSP and RRP RSAC processes on how to implement section 20156(g). FRA worked with the System Safety Task Group to receive input regarding how the consultation process should be addressed, with the understanding that the same language would be included in both the SSP and RRP NPRMs for review and comment.

E. Related Fatigue Management Plans Rulemaking

Section 20156(d)(2) states that a SSP must include a fatigue management plan that meets the requirements of section 20156(f). This SSP final rule does not address this mandate because it is currently being considered by a separate rulemaking process.

On December 8, 2011, the RSAC voted to establish a Fatigue Management Plans Working Group (FMP Working Group). The purpose of the FMP Working Group is to provide "advice regarding the development of implementing regulations for Fatigue Management Plans and their deployment under the Rail Safety Improvement Act of 2008." *Railroad Safety Advisory Committee Task Statement: Fatigue Management Plans,* Task No.: 11–03, Dec. 8, 2011. Specifically, the FMP Working Group is tasked to: "review the mandates and objectives of the [RSIA] related to the development of Fatigue Management Plans, determine how medical conditions that affect alertness and fatigue will be incorporated into Fatigue Management Plans, review available data on existing alertness strategies, consider the role of innovative scheduling practices in the reduction of employee fatigue, and review the existing data on fatigue countermeasures." *Id.*

The working group completed its work in September 2013 and submitted its recommendations to FRA for further consideration. Ultimately, any fatigue management plans required by FRA pursuant to section 20156(d)(2) and 20156(f) would be considered part of a railroad's overall SSP.

FRA notes that the SSP NPRM had a placeholder in proposed § 270.103(t) that would require a railroad, as part of its SSP, to develop a fatigue management plan no later than three years after the effective date of the final rule, or three years after commencing operations, whichever is later. This placeholder did not contain any additional substantive requirements and was intended merely to be an acknowledgement of the statutory fatigue management plan mandate. FRA has elected to not include this placeholder in the final rule because it may create confusion regarding the separate FMP Working Group process and the ongoing fatigue management plans rulemaking.

IV. Guidance Manual

The preamble of the SSP NPRM outlined FRA's plan to publish a guidance manual that would assist in the development, implementation, and evaluation of a railroad's SSP. FRA believes sufficient guidance is currently available to railroads that would assist in implementing a SSP. As discussed previously, a majority of passenger railroads affected by this rule participate in the APTA system safety program and are currently participating in the APTA audit program. APTA has published significant guidance regarding its program, primarily, APTA's Manual for the Development of System Safety Program Plans for Commuter Railroads. APTA, *Manual for the Development of System Safety Program Plans for Commuter Railroads,* (May 15, 2006), available on APTA's Web site at *http://www.apta.com/resources/reportsandpublications/Pages/Rail.aspx.* FRA has also developed guidance regarding implementing system safety principals in its Collision Hazard Analysis Guide. The Collision Hazard Analysis Guide supports APTA's Manual by providing a "step-by-step procedure on how to perform hazard analysis and how to develop effective mitigation strategies that will improve passenger rail safety." FRA, *Collision Hazard Analysis Guide: Commuter and Intercity Passenger Rail Service,* 5 (October 2007), available at *www.fra.dot.gov.* FRA believes APTA's guidance on its system safety program and FRA's Collision Hazard Analysis Guide would provide the necessary assistance to railroads implementing a SSP. As noted previously, FRA will work with each railroad to provide the necessary assistance and guidance for implementing a SSP.

V. Discussion of Specific Comments and Conclusions

FRA received 19 written comments in response to the NPRM, including comments from members of the railroad industry, trade organizations, labor organizations, as well as members of the general public. Specifically, comments were received from the following organizations: Alaska Railroad Corporation, American Association for Justice, Amtrak, Association of American Railroads (AAR), APTA, Maelstrom Society, National Safety Council, New York State Metropolitan Transportation Authority (MTA), Northeast Illinois Regional Commuter Railroad Corporation (Metra), Parsons Brinkerhoff, Inc., and Trinity Railway Express. Interested labor organizations (Labor Organizations) jointly filed a comment. The Labor Organizations included: American Train Dispatchers Association, Brotherhood of Locomotive Engineers and Trainmen, Brotherhood of Maintenance of Way Employes Division, Brotherhood Railway Carmen Division TCU/IAM, Sheet Metal, Air, Rail and Transportation Workers, and Transportation Workers Union of America (TWU). The following discussion provides an overview of the written comments FRA received in response to the NPRM. More detailed discussions of specific comments and how FRA has chosen to address these comments in the final rule can be found in the relevant section-by-section analysis portion of this preamble.

Generally, all of the comments submitted were in favor of SSP. While the comments varied on the structure and breadth of a SSP, there was agreement that a properly implemented SSP would increase safety of the railroad's operations. As discussed previously, there are two concurrent rulemakings that will implement sections 20156, 20118, and 20119, the SSP rule and the RRP rule. FRA established separate safety risk reduction rules for passenger railroads and the Class I freight railroads to account for significant differences between passenger and freight operations. Many commenters requested that FRA make it clear that the SSP requirements are separate from the forthcoming RRP rule and a railroad will not be required to submit both a SSP plan and RRP plan to FRA. It is not the intent that one railroad will be required to satisfy both regulations, *i.e.,* be required to implement both a SSP and RRP and submit the corresponding plans to FRA for review and approval.

Certain commenters provided specific scenarios involving multiple rail operations and inquired which railroad would be required to comply with which regulation. One example involved a commuter railroad subject to the SSP rule that contracts certain portions of its passenger operations to a freight railroad that may be subject to the proposed RRP rule. In this scenario, the entity that is ultimately responsible for providing the passenger service would be responsible for complying with the SSP rule, which would be the commuter railroad. The fact that the commuter railroad contracts its operations to the freight railroad does not result in the delegation of the duty to comply with the SSP rule to that freight railroad. Contracting out these operations may pose certain hazards and risks. Therefore, the commuter railroad's SSP needs to take into account that the passenger operations are contracted out to another railroad. If the freight railroad also conducts freight operations over the same track in which it conducts the passenger operations for the commuter railroad and the freight railroad is required to implement a RRP, that segment will be included in the freight railroad's RRP and must take into consideration the risks and hazards posed by the passenger operation. Further, if the freight railroad conducts freight operations over the same track in which it conducts the passenger operations for the commuter railroad, the commuter railroad's SSP must take into consideration the risks and hazards posed by the freight operations.

Another commenter presented the scenario in which a passenger railroad subject to the SSP rule owns and maintains, but does not dispatch, a segment of track in which there are freight operations. From the example, it is not clear if the passenger railroad is also operating on that segment. If the passenger railroad is operating on that segment, pursuant to § 270.3(a), it will need to include that segment in its SSP. If the passenger railroad is not operating on that segment of track, but there are freight operations on that segment of track by another railroad, the passenger railroad will include that segment in its SSP because, as discussed in the section-by-section analysis for § 270.103(d)(2), the passenger railroad will be required to identify the persons that utilize significant safety-related services and by operating on track that the passenger railroad owns and maintains, the freight operators are utilizing significant safety-related services of the passenger railroad. Further, FRA would expect the passenger railroad to include that segment in the description of its rail system pursuant to § 270.103(d)(1). The railroad conducting freight operations on that segment of track may be required to implement a RRP and that segment may need to be included in its RRP.

Another example was a situation in which a passenger railroad has two terminals on its system where there are freight operations adjacent (within 25') to the passenger operations. In this scenario, FRA would expect the passenger railroad's SSP to assess what hazards and resulting risks arise due to the proximity of the freight operations to the passenger operations; however, the actual freight operations would not be included in the passenger railroad's SSP. FRA does not intend these three examples to cover every scenario a railroad may encounter; rather, these examples provide guidance concerning what facts FRA will find determinative regarding which railroad will be required to comply with which regulation. Since FRA cannot contemplate every scenario, railroads and other interested parties are welcomed and encouraged to reach out to FRA for guidance regarding application of the SSP rule to a railroad's specific operations.

In many instances in the NPRM, FRA stated that it plans on working with the railroads on certain aspects of the rule. The Labor Organizations expressed concern that FRA plans on exclusively working with the railroads and not allowing any other interested party to be involved, effectively substituting FRA for the Labor Organizations in the statutory-mandated consultation role. This was not FRA's intent behind those statements. Rather, the intent was to make it clear that FRA would be available to provide guidance to the railroads on the various aspects of the rule, not that there would be an exclusive partnership between FRA and the railroads to develop the railroads' SSPs. FRA will work with the railroads and will not replace the Labor Organizations and any other directly affected employee in their consultation role. FRA has amended the language to make this intention clear. It is also important to note that through the consultation process in § 270.107, railroad employees will always have an opportunity to provide input on the railroads' SSPs.

The Labor Organizations also believe that the NPRM supports a continuation of self-analysis by the railroads, which, they claim, is inconsistent with the intent behind RSIA. As evidence, the Labor Organizations point to multiple instances in the NPRM where FRA states that railroads have flexibility and/or discretion to make certain determinations on certain requirements of the rule, such as the waiver section proposed in § 270.7, the lack of a penalty schedule in the NPRM, and that, in limited instances, a railroad is allowed to make safety-critical changes to its SSP without prior FRA approval.

The SSP rule is directly dependent on a railroad's ability to thoroughly and candidly assess its hazards and resulting risks. The SSP requires a railroad to engage in self-analysis that will be conducted in conjunction with the railroad's directly affected employees and FRA oversight. Since no two railroads operations are exactly the same, no SSP will be exactly the same, which means that a railroad will need a certain degree of flexibility to tailor a SSP to its specific operations. Regardless of the amount of flexibility afforded to the railroads, the directly affected employees, including the Labor Organizations, will have an opportunity to provide input and work with the railroads on the development of the SSP. Regarding the lack of a penalty schedule, FRA typically does not include penalty schedules in an NPRM; however, this final rule does include a penalty schedule.

APTA expressed concern that the proposed rule was more prescriptive in significant respects than current FRA practices. APTA believes that the level of specificity in the proposed rule diminishes the flexibility needed so that the railroads can adapt their SSP plans to local conditions. Further, APTA states such specificity could divert a railroad's attention from assessing its operation risk to assessing regulatory compliance risk and would only expand the amount of paper and bureaucracy needed to comply with the rule with little to no increase in safety. APTA believes that FRA has expanded the elements of the APTA program which threatens to divert attention from the railroad's core safety practices and the highest risk of railroad operations. As examples, APTA points to the requirements associated with scheduling, reporting, and conducting consultation with the directly affected employees pursuant to § 270.102; defining, outlining, measuring, and promoting a positive safety culture pursuant to § 270.103(c) and (v); the concept of fully implemented; and the requirement that the railroad establish milestones to track the progress of implementation. Each one of these examples, according to APTA, is an instance in which railroads may have a different understanding of the requirement and therefore, subjectivity is introduced into the process and does not support a consistent regulatory framework.

FRA disagrees with APTA's assertions. As discussed above, the SSP rule is structured so that a railroad can tailor the program to its operations. The SSP rule sets forth general parameters and the railroad will design its program so that it fits these parameters, addresses the railroad's operations, and eliminates or reduces hazards on the railroad's operations. As with most new FRA regulations, significant interaction between FRA, the railroads, and other stakeholders will be necessary to ensure all parties understand the proper implementation for the rule. The majority of railroads that are required to comply with this rule already participate in APTA's system safety program. FRA believes that this rule does not add a significant paperwork and bureaucracy burden compared to what is already required by APTA's program. FRA does not believe the rule is more directive than the APTA program; rather, since most of the railroads that will implement a SSP already participate in the APTA program, the railroads are familiar with the concept and application of system safety and will be ready to adapt their existing APTA program to the requirements set forth in this rule. Further, implementation of the SSP rule will more than likely be the railroad conducting a gap analysis between its current APTA program and the SSP rule and modifying that program where necessary to bring it into compliance with the SSP rule.

The majority of the comments supported and understood that the discovery protections are necessary for a railroad to engage in a thorough and candid analysis of the hazards and resulting risks on its system; however, the American Association for Justice (AAJ) objected to the inclusion of any information protections. AAJ claims that: (1) The proposed information protections are unprecedented; (2) FRA can promulgate a SSP regulation without the information protections; (3)

the information protections will reduce the rights of persons injured in railroad accidents; (4) the information protections will allow railroads to hide safety hazards; and (5) FRA should specifically preserve State tort law based claims.

First, AAJ claims that proposed information protections are unprecedented. AAJ recognizes that there are existing programs that have information protections; however, AAJ argues that these programs have two key features: (1) Congress directed that disclosure of documents be limited, and (2) limited disclosure applies predominately to documents actually submitted to a federal agency. AAJ believes that the SSP information protections do not have either of these key features.

While Congress did not set forth specific information protections in section 20119, Congress gave FRA authority to set forth such specific protections. As discussed previously, in section 20119(a), Congress directed FRA to conduct a study to determine if certain information protections would be in the public interest. Congress set forth the specific parameters of the information protections that the study must consider. Congress then authorized FRA to promulgate a rule, subject to notice and comment, which addressed the results of the study. *Id.* FRA has complied with Congress' mandate and has set forth information protections that are consistent with the specific parameters set forth by Congress. FRA does not believe that the information protections are invalid simply because Congress didn't promulgate specific protections.

Nothing in section 20119 limits the information protections to documents that are submitted to FRA. The language used by Congress in section 20119 indicates the information protections, depending on the results of the study, could apply to information that may not even be submitted to FRA. Pursuant to section 20119(a), the study must consider information protections that would apply to documents that are compiled and collected for "the purpose of planning, implementing, or evaluating a safety risk reduction program." Since Congress did not limit the information protections only to documents that are submitted to FRA, it is within FRA's authority to set forth information protections that apply to documents within a railroad's possession.

Nothing in 23 U.S.C. 409 (section 409), the statute that SSP information protections are modeled after, or the Supreme Court's decision in *Guillen* (which reviewed the validity and constitutionality of section 409), limits the information protections to documents submitted to the Federal Highway Administration (FHWA).[5] The Court's interpretation of section 409 was not based on whether the documents were submitted to FHWA. Rather, the Court held that the information protections were extended to the information because the Hazard Elimination Program required compiling or collection of that information. *Pierce County* v. *Guillen,* 537 U.S. 129, 146 (2003). In the case of the SSP, the railroads are required by statute to compile and collect information for a SSP, so, like section 409 and the holding in *Guillen,* the protections are extended to that information.

AAJ claims that in the limited circumstances in which data has been protected, the provisions have been narrowly tailored and construed. AAJ believes that SSP information protections are overly broad and inconsistent with any other government program that limits some disclosure of evidence.

FRA agrees with AAJ's assertion that the SSP information protections must be narrowly tailored and construed. In *Guillen,* the Court recognized that "statutes establishing evidentiary privileges must be construed narrowly because privileges impede the search for truth." *Guillen* at 144–45. Since section 409 established a privilege, the Court construed it narrowly to the extent the text of the statute permitted. *Id.* at 145. FRA believes the SSP information protections are consistent with the Court's narrow interpretation of section 409.

Furthermore, the SSP protections are more narrowly tailored than the protections in section 409. Section 270.105(a)(2) limits the protections to information that was originally compiled and collected "solely" for the purpose of planning, implementing or evaluating a SSP. This means that information compiled or collected for any other purpose is not protected, even if the railroad also uses that information for its SSP. For example, if a railroad is required by another provision of law or regulation to compile or collect information, the information protections do not apply to that information. "Solely" also means that a railroad must continue to use that information only for its SSP. If a railroad subsequently uses for any other purpose information that was initially compiled or collected for a SSP, that information is not protected to the extent that it is used for the non-SSP purpose. These additional limits result in protections that are more narrow and specific than those in section 409, which does not include any language similar to "solely" that would limit protected information to information generated only for the exclusive purpose of the Hazard Elimination Program.

Second, AAJ contends that FRA can issue a SSP rule without the discovery protections, just like FAA did in its SMS rulemaking. A significant difference between the FRA and FAA programs is the scope of statutory authority Congress gave each agency for protection of information collected or maintained as part of an SMS. The FAA's authority, set forth in 49 U.S.C. 44735, limits the protection of SMS data that is voluntarily submitted, such as reports, data, or other information produced or collected for purposes of developing and implementing an SMS, from FOIA disclosure by the FAA. FRA's authority to implement SMS information protections is based on 49 U.S.C. 20119, and recommendations resulting from the required study under section 20119.

As discussed previously, the Study concluded that it would be within FRA's authority and in the public interest for FRA to promulgate a regulation protecting certain risk analysis information held by the railroads from discovery and use in litigation and makes recommendations for the drafting and structuring of such a regulation. *See Study of Existing Legal Protections for Safety-Related Information and Analysis of Considerations For and Against Protecting Railroad Safety Risk Reduction Program Information* at 63–64. Therefore, FRA believes the information protections are consistent with the authority provided by Congress as set forth in 49 U.S.C. 20119 and the conclusion of the Study.

Third, AAJ believes the SSP information protections will reduce the rights of persons injured in railroad accidents. AAJ points to the fact that in many cases, evidence a railroad knew or should have known of a hazard is the key to proving the railroad's liability, particularly for Federal Employers Liability Act cases. AAJ believes that the study concluded without analysis that injured people could continue to be able to pursue legal remedies because access to documents that are currently discoverable would remain discoverable. AAJ does not believe this conclusion is accurate because the information protections may shield the documents/data necessary to show that the railroad knew or should have known of the hazard.

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[5] Section 409 and *Guillen* are discussed extensively in the section-by-section analysis of § 270.105.

The SSP information protections have been drafted with the goal that a plaintiff is no worse off than they would have been had the SSP rule never existed. This is consistent with section 409 and the Court's interpretation of that section. *See Guillen* at 146. To ensure a plaintiff is no worse off, § 270.105(b) sets forth certain exceptions to the information protections. Pursuant to § 270.105(b), the information protections are not extended to information compiled or collected for a purpose other than that specifically identified in § 270.105(a). Further, if certain information was discoverable and admissible before the enactment of the SSP rule protections, § 270.105(b) ensures that the information remains discoverable and admissible. These exceptions are discussed extensively in the section-by-section analysis for § 270.105(b). FRA believes that these exceptions strike an appropriate balance between ensuring that plaintiffs are no worse than they would have been if the SSP rule had not existed and encouraging the railroads to make a robust and candid assessment of the hazards and resulting risks on their system.

According to AAJ, the information protections will allow railroads to hide safety hazards. AAJ believes that the threat of disclosure of these hazards creates an incentive for railroads to correct them immediately. AAJ points to multiple cases that they believe provide proof that railroads routinely hide evidence of hazards.

FRA disagrees with this assertion. The purpose of the SSP is for railroads to identify hazards and resulting risks on their system and take the appropriate measures to mitigate or eliminate these hazards. Without the information protections, a SSP could result in an effort-free tool for plaintiffs in litigation against railroads, which would discourage railroads from identifying hazards and resulting risks, thus frustrating the intent behind section 20156. FRA believes that the SSP and information protections will encourage railroads to identify and address, rather than hide, hazards. Furthermore, if a railroad is already required by another law or regulation to collect information to show compliance with existing laws or regulations, that information will not be protected. Therefore, railroads will not be able to use the SSP information protections to hide issues of non-compliance.

Finally, AAJ requests that FRA specifically preserve state tort law based claims. AAJ believes that since railroads are required to submit their SSP plans to FRA for approval, railroads may claim that they are immune from any safety hazard claim or either that the state law claim is preempted by FRA's approval of the SSP.

This concern was also raised by the Labor Organizations. To address this issue, FRA included § 270.201(b)(4) in the final rule, which provides that approval of a railroad's SSP plan under this part does not constitute approval of the specific actions the railroad will implement under its SSP plan pursuant to § 270.103(q)(2) and shall not be construed as establishing a Federal standard regarding those specific actions.

FRA will not review or approve the specific mitigation and elimination measures that a railroad may adopt to address the hazards and risks that it identifies. *See* § 270.201(a)(2). The SSP rule is not intended to preempt State standards of care regarding the specific risk mitigation actions a railroad will implement under its SSP. Accordingly, § 270.201(b)(4) clarifies that FRA approval of a railroad's SSP plan under this final rule does not constitute approval of the specific mitigation and elimination measures that the railroad will implement pursuant to § 270.103(q)(2) and should not be construed as establishing a Federal standard of care regarding those specific actions.

VI. Section-by-Section Analysis

FRA is adding a new part 270 to title 49 of the CFR. Part 270 satisfies the statutory requirements regarding safety risk reduction programs for railroads providing intercity rail passenger or commuter rail passenger service. *See* 49 U.S.C. 20156. Part 270 also protects certain information compiled or collected pursuant to a safety risk reduction program from admission into evidence or discovery during certain court proceedings for damages. *See* 49 U.S.C. 20119.

Subpart A—General

Section 270.1 Purpose and Scope

This section contains a formal statement of the final rule's purpose and scope and remains unchanged from the NPRM. Paragraph (a) states that the purpose of the rule is to improve railroad safety through structured, proactive processes and procedures developed and implemented by railroads. The rule requires a railroad to establish a program that systematically evaluates railroad safety hazards and the resulting risks on its system and manages those risks in order to reduce the number and rates of railroad accidents, incidents, injuries, and fatalities.

Paragraph (b) states that the rule prescribes minimum Federal safety standards for the preparation, adoption, and implementation of railroad system safety programs. The rule does not restrict railroads from adopting and enforcing additional or more stringent requirements not inconsistent with this part.

Paragraph (c) explains that the rule provides for the protection of information generated solely for the purpose of developing, implementing, or evaluating a system safety program under this part. In addition to the SSP, § 270.1(c) of the NPRM proposed implementing protection of information for a railroad safety risk reduction rule required by FRA for Class I freight railroads and railroads with in adequate safety performance, *i.e.*, the RRP rule. 77 FR 55379. Upon further consideration, FRA has determined that the RRP protections should be implemented in the RRP final rule, not in this rule. Accordingly, this section has been revised to only apply to this SSP final rule.

NY MTA recommended that the term "solely" be deleted from paragraph (c) and § 270.105(a) to protect studies or risk analyses that are not developed expressly to comply with this part. NY MTA believes that it is in the public interest to ensure that railroads conduct on-going and thorough self-critical examinations and expressed concern that if these types of studies or analyses are not protected, they may be used against the railroad in a court proceeding. As discussed further in the section-by-section analysis for § 270.105, FRA only has the authority under section 20119(b) to protect documents that are created pursuant to a SSP; therefore, deleting the term "solely" would improperly expand the protections beyond the limits of FRA's authority.

Section 270.3 Application

This section sets forth the applicability of the rule and remains unchanged from the NPRM. Section 20156(a)(1) mandates that FRA require each Class I railroad, a railroad carrier that has inadequate safety performance, or a railroad that provides intercity rail passenger or commuter rail passenger transportation to establish a railroad safety risk reduction program. This rule sets forth the requirements of a railroad safety risk reduction program for a railroad that provides intercity rail passenger or commuter rail passenger transportation. Safety risk reduction programs for Class I railroads and railroads with inadequate safety performance will be addressed in the separate RRP rulemaking proceeding. *See* 80 FR 10950 (RRP NPRM).

Paragraph (a) explains that this rule applies to railroads that operate intercity or commuter passenger train service on the general railroad system of transportation and railroads that provide commuter or other short-haul rail passenger train service in a metropolitan or suburban area (as described by 49 U.S.C. 20102(2)), including public authorities operating passenger train service. A public authority that provides passenger commuter train service by contracting out the actual operation to another railroad or independent contractor is regulated by FRA as a railroad under the provisions of the rule. Although the public authority is ultimately responsible for the development and implementation of a SSP (along with all related recordkeeping requirements), the railroad or other independent contractor that operates the authority's commuter passenger train service is expected to comply with the SSP established by the public authority, including implementation of the SSP plan.

In commenting on the NPRM, the Alaska Railroad proposed that when FRA next submits technical corrections of Federal statutes to Congress, FRA no longer use the terms "intercity passenger" and "commuter passenger" and instead use the term "passenger" to refer to these type of railroads. The Alaska Railroad believes that the terms, "intercity passenger" and "commuter passenger," are based on an old, outdated statutory context. While FRA does not agree or disagree with the Alaska Railroad's position regarding the use of these terms, FRA agrees with the Alaska Railroad that this issue is a matter to be handled legislatively by Congress—not a matter to be handled by FRA in a rulemaking.

AAR expressed concern that paragraph (a) could lead to confusion that certain freight railroads may be required to have a SSP in addition to a RRP because some freight railroads operate commuter trains on behalf of commuter agencies and some freight railroads provide tracks over which passenger trains operate. To avoid confusion, AAR proposed that "railroads that primarily provide freight service and are potentially subject to risk reduction program regulations" should be excepted from the rule. The discussion of comments section addressed multiple scenarios raised by commenters that involve freight operations and passenger operations and which railroad would be responsible for which program. Simply because a passenger railroad contracts out passenger service to a freight railroad does not mean the duty to comply with this rule has been automatically delegated to the freight railroad and the passenger railroad no longer is required to comply with this rule. The passenger railroad ultimately is responsible for complying with this rule and the freight railroad providing the passenger service is required to comply with the passenger railroad's SSP. *See* § 270.7(b). FRA believes that AAR's suggested language would only lead to further confusion rather than clarification. It is not clear which railroads would be classified as "primarily provid[ing] freight service" and, therefore, it would not be clear which railroad would be excepted from complying with this rule. Due to this ambiguity, AAR's suggested language is not adopted.

Metra requested that an RSAC recommendation regarding delegation of duties under this rule be inserted into the final rule. The RSAC recommended that if a passenger railroad contracts all activities that relate to the passenger service to another entity, the sponsoring passenger railroad may seek approval from the FRA Associate Administrator of Safety to delegate responsibility for the SSP to the other entity. FRA chose not to adopt this recommendation. It would not be consistent with FRA's statutory jurisdiction over passenger railroads to allow delegation of responsibility under this part, so that a passenger railroad could effectively divest itself of legal responsibility under the rule. In certain instances, including this part, FRA allows a railroad to contract with another entity to perform the duties required by a rule; however, FRA's approach has always been never to allow a railroad to delegate completely responsibility for compliance with a rule to another entity. Since the SSP rule is the first of its kind for FRA and the railroad industry, FRA believes it is important for the passenger railroad to be responsible for compliance with the rule to ensure that the railroad is involved in system safety planning and implementation under the rule.

In paragraph (b), certain railroads are excepted from the final rule's applicability. The exceptions proposed in the NPRM are adopted in the final rule. The first exception, in paragraph (b)(1), covers rapid transit operations in an urban area that are not connected to the general railroad system of transportation. This paragraph clarifies the circumstances under which rapid transit operations are not subject to FRA jurisdiction under this part. It should be noted, however, that some operations having rapid transit characteristics are within FRA's jurisdiction given their connections to the general system, *e.g.,* shared use of the general system right-of-way. FRA specifically intends for part 270 to apply to such operations.

Paragraph (b)(2) sets forth an exemption for operations commonly described as tourist, scenic, historic, or excursion service whether on or off the general railroad system. Tourist, scenic, historic, or excursion rail operations is defined in § 270.5. This exemption is consistent with the treatment of tourist, scenic, historic, or excursion rail operations in FRA's other regulations concerning passenger operations, including the underlying basis for the regulatory approach taken in those regulations. *See* 49 CFR 238.3(c)(3), 64 FR 25576 (May 12, 1999); and 239.3(b)(3), 63 FR 24644 (May 4, 1998).

Paragraph (b)(3) makes clear that the requirements of the rule do not apply to the operation of private passenger train cars, including business or office cars and circus train cars. While FRA believes that a private passenger car operation should be held to the same basic level of safety as other passenger train operations, such operations were not specifically identified in the statutory mandate and FRA is taking into account the burden that would be imposed by requiring private passenger car owners and operators to conform to the requirements of this part. Private passenger cars are often hauled by host railroads, such as Amtrak and commuter railroads, and these hosts often impose their own safety requirements on the operation of the private passenger cars. Pursuant to this rule, these host railroads are required to have SSPs in place to protect the safety of their own passengers; in turn, the private car passengers benefit from these programs even without the rule directly covering private car owners or operators. In the case of non-revenue passengers, including employees and guests of railroads that are transported in business and office cars, as well as persons traveling on circus trains, the railroads are expected to provide for their safety consistent with existing safety operating procedures and protocols for normal train operations.

Finally, paragraph (b)(4) sets forth an exception from the requirements of this part for railroads that operate only on track inside an installation that is not part of the general railroad system of transportation (*i.e.,* plant railroads, as defined in § 270.5). Plant railroads are typified by operations such as those in steel mills that do not go beyond the plant's boundaries and that do not involve the switching of rail cars for entities other than themselves.

Section 20156(a)(4) allows a railroad carrier that is not required to submit a railroad safety risk reduction program to voluntarily submit such a program. If the railroad voluntary submits a program, it shall comply with the requirements set forth in section 20156 and is subject to approval by the Secretary. In the NPRM, FRA sought comment on whether a provision that allows a railroad to establish voluntarily a SSP should be added to the final rule. FRA did not receive a significant number of comments in response to this request and the comments FRA did receive, supported voluntary compliance with the rule.

As discussed in the NPRM, FRA anticipates that the majority of railroads which voluntarily submit a railroad safety risk reduction program under section 20156(a)(4) would do so pursuant to the RRP regulation that is the subject of a separate proceeding. Paragraph (a) is broad and intended to cover the majority of the railroads that provide commuter and intercity passenger service. Absent the exceptions in paragraph (b), if a railroad is not required by this part to establish a SSP, that railroad more than likely does not provide commuter and intercity passenger service and, therefore, may be required to establish a RRP. If these railroads are not required to establish a RRP but decide to voluntarily establish a railroad safety risk reduction program pursuant to section 20156(a)(4), the RRP regulation would more than likely be better suited for their operations because, due to the breadth of paragraph (a), they are most likely not a railroad that provides commuter or intercity passenger service. Therefore, FRA believes voluntary compliance with a statutory-mandated risk reduction program, including a SSP, is better addressed in the forthcoming RRP rule. *See* 80 FR 10969 and 10992 for the proposed RRP voluntary compliance section and discussion.

Section 270.5 Definitions

This section contains a set of definitions that clarify the meaning of important terms as they are used in the rule. The definitions are carefully worded in an attempt to minimize the potential for misinterpretation of the rule. Many of the definitions are based on definitions in FTA's part 659 and APTA's system safety program. In the NPRM, FRA requested comment and input regarding the proposed terms defined in this section and specifically whether other terms should be defined. FRA received multiple comments in response to this request. Generally, commenters did not have significant issues with the proposed definitions; however, some commenters recommended adding definitions for certain terms.

The Labor Organizations suggested that FRA add the definitions that the RSAC recommended but FRA chose not to include in the NPRM. The definitions were for the following terms: Contractor, FTA, hazard analysis, improvement plan, individual investigation, passenger operations, passenger railroad, railroad property, risk-based hazard management, safety, safety certification, safety culture, safety-related services, safety-related employee, sponsoring railroad, system safety program, and system safety program plan. Trinity Railways also requested that FRA add definitions for passenger railroad, safety-related services, and sponsoring railroad. Regarding the terms FTA, individual investigation, passenger operations, railroad property, safety-related employee, and sponsoring railroad, FRA declines to add definitions for these terms because these terms are not used in the rule text. Regarding the terms contractor and safety, these terms have a common understanding throughout the railroad industry and do not have a particular meaning within the rule, so definitions for these terms are not necessary. Regarding the terms hazard analysis, improvement plan, passenger railroad, safety certification, and safety-related services, there are sections within the rule that address the meaning of each term and FRA believes that it is unnecessary to include definitions for these terms as well. *See* §§ 270.3(a), 270.103(d)(2) and (3), (q), and (s)(3), 270.303(b)(4), and 305(b)(1). However, FRA has decided to add definitions for the terms risk-based hazard management, safety culture, system safety program, and system safety program plan. A discussion of all the definitions used in this part follows.

"Administrator" refers to Federal Railroad Administrator or his or her delegate.

"Configuration management" means the process a railroad uses to ensure that the configurations of all property, equipment and system design elements are properly documented.

"FRA" means the Federal Railroad Administration.

"Fully implemented" means that all the elements of the railroad's SSP plan required by this part are established and applied to the safety management of the railroad. APTA commented that the proposed definition for "fully implemented" included two sentences and that each sentence provided the same information but in a different context and that this could lead to confusion as to how it should be applied. However, FRA notes that the proposed definition contained only one sentence and believes that it was sufficiently clear to avoid confusion. APTA may have been referring to the section-by-section analysis discussion for this definition. In this regard, FRA has not included that additional discussion here to maintain clarity.

"Hazard" means any real or potential condition, as identified in the railroad's risk-based hazard analysis under § 270.103(q), that can cause injury, illness, or death; damage to or loss of a system; or damage to equipment, property, or the environment. This definition is based on the existing definition of the term in FTA's part 659. 49 CFR 659.5. FRA does not intend this definition to include hazards that are completely unrelated to railroad safety, such as environmental hazards that would fall under the exclusive jurisdiction of the United States Environmental Protection Agency (EPA) or workplace safety hazards that would fall under the exclusive jurisdiction of the United States Department of Labor's Occupational Safety and Health Administration (OSHA). Railroad safety hazards that fall under FRA jurisdiction that could cause damage to the environment, however, would be included in this definition. For example, the potential of a derailment of a tank car at a location due to track geometry would fall under this definition. If that derailment would not likely result in a release of hazardous materials, it would fall under FRA's jurisdiction. However, if the derailment has a high potential for the release of hazardous material, that would be a hazard that would fall under this definition that is related to railroad safety and may fall under both FRA's and EPA's jurisdiction. An example of a railroad hazard that would fall exclusively under EPA's jurisdiction is air pollution caused by locomotive emissions. This hazard is not within FRA's jurisdiction and would not be included in this definition. *See e.g.*, 40 CFR part 92 (Control of Air Pollution from Locomotives and Locomotive Engines).

"Passenger" means a person, excluding an on-duty employee, who is on board, boarding, or alighting from a rail vehicle for the purpose of travel. This definition is modeled after the definition of "passenger" in FTA's regulations at part 659, which defines a "passenger" as "a person who is on board, boarding, or alighting from a rail transit vehicle for the purpose of travel." 49 CFR 659.5. FRA has added the phrase "excluding an on-duty employee" to the definition to clarify that, if a person is engaging in these activities (on board, boarding, or alighting) and they are an off-duty railroad employee, that person is considered a passenger for the purposes of this rule.

"Person" means an entity of any type covered under 1 U.S.C. 1, including, but not limited to, the following: A railroad; a manager, supervisor, official, or other employee or agent of a railroad; any owner, manufacturer, lessor, or lessee of railroad equipment, track, or facilities; any independent contractor or subcontractor providing goods or services to a railroad; and any employee of such owner, manufacturer, lessor, lessee, or independent contractor or subcontractor.

"Plant railroad" means a type of operation that has traditionally been excluded from the application of FRA regulations because it is not part of the general railroad system of transportation. Under § 270.3, FRA has chosen to exempt plant railroads, as defined in § 270.5, from the regulation. In the past, FRA has not defined the term "plant railroad" in other regulations that it has issued because FRA assumed that its *Statement of Agency Policy Concerning Enforcement of the Federal Railroad Safety Laws, The Extent and Exercise of FRA's Safety Jurisdiction,* 49 CFR part 209, Appendix A (FRA's Policy Statement or the Policy Statement) provided sufficient clarification as to the meaning of that term. However, it has come to FRA's attention that certain rail operations believed that they met the characteristics of a plant railroad, as set forth in the Policy Statement, when, in fact, their rail operations were part of the general railroad system of transportation (general system) and therefore did not meet the definition of a plant railroad. FRA would like to avoid any confusion as to what types of rail operations qualify as plant railroads. FRA would also like to save interested persons the time and effort needed to cross-reference and review FRA's Policy Statement to determine whether a certain operation qualifies as a plant railroad. Consequently, FRA has decided to define the term "plant railroad" in part 270.

The definition clarifies that when an entity operates a locomotive to move rail cars in service for other entities, rather than solely for its own purposes or industrial processes, the services become public in nature. Such public services represent the interchange of goods, which characterizes operations on the general system. As a result, even if a plant railroad moves rail cars for entities other than itself solely on its property, the rail operations will likely be subject to FRA's safety jurisdiction because those rail operations bring plant trackage into the general system.

The definition of the term "plant railroad" is consistent with FRA's longstanding policy that it will exercise its safety jurisdiction over a rail operation that moves rail cars for entities other than itself because those movements bring the track over which the entity is operating into the general system. *See* 49 CFR part 209, Appendix A. Indeed, FRA's Policy Statement provides that "operations by the plant railroad indicating it [i]s moving cars on . . . trackage for other than its own purposes (*e.g.,* moving cars to neighboring industries for hire)" brings plant track into the general system and thereby subjects it to FRA's safety jurisdiction. 49 CFR part 209, Appendix A. Additionally, this interpretation of the term "plant railroad" has been upheld in litigation before the U.S. Court of Appeals for the Fifth Circuit. *See Port of Shreveport-Bossier* v. *Federal Railroad Administration,* No. 10–60324 (5th Cir. 2011) (unpublished per curiam opinion). APTA believes that since the term "plant railroad" is provided in support of 49 CFR part 209 it does not need to be defined within the context of the SSP rule. FRA disagrees. Plant railroads will be exempt from the rule; therefore, FRA believes it is necessary to clearly define what type of operations will be considered a "plant railroad."

"Positive train control system" means a system designed to prevent train-to-train collisions, overspeed derailments, incursions into established work zone limits, and the movement of a train through a switch left in the wrong position, as described in subpart I of 49 CFR part 236. APTA believes that since the term "positive train control" is provided in support of 49 CFR part 236 it does not need to be defined within the context of the SSP rule. FRA disagrees. Since "positive train control system" has a specific meaning within FRA's regulations, it is important that the meaning of the term used within the SSP rule is consistent with part 236.

"Rail vehicle" means railroad rolling stock, including, but not limited to, passenger and maintenance vehicles.

"Railroad" means: (1) Any form of non-highway ground transportation that runs on rails or electromagnetic guideways, including—

(i) Commuter or other short-haul rail passenger service in a metropolitan or suburban area and commuter railroad service that was operated by the Consolidated Rail Corporation on January 1, 1979; and

(ii) High speed ground transportation systems that connect metropolitan areas, without regard to whether those systems use new technologies not associated with traditional railroads, but does not include rapid transit operations in an urban area that are not connected to the general railroad system of transportation; and

(2) A person or organization that provides railroad transportation, whether directly or by contracting out operation of the railroad to another person.

The definition of "railroad" is based upon 49 U.S.C. 20102(1) and (2), and encompasses any person providing railroad transportation directly or indirectly, including a commuter rail authority that provides railroad transportation by contracting out the operation of the railroad to another person, and any form of non-highway ground transportation that runs on rails or electromagnetic guideways, but excludes urban rapid transit not connected to the general system.

"Risk" means the combination of the probability (or frequency of occurrence) and the consequence (or severity) of a hazard.

"Risk-based hazard management" means the processes (including documentation) used to identify and analyze hazards, assess and rank corresponding risks, and eliminate or mitigate the resulting risks. This is a high-level definition of "risk-based hazard management" and will provide a general understanding of the concept of what is "risk-based hazard management." Risk-based hazard management is a key component of a railroad's SSP and § 270.103(p) sets forth the requirements for a risk-based hazard management program.

"Safety culture" means the shared values, actions and behaviors that demonstrate commitment to safety over competing goals and demands. This definition was proposed in the NPRM section-by-section analysis of § 270.101(b). This definition is from the DOT Safety Council's May 2011 research paper, *SAFETY CULTURE: A Significant Driver Affecting Safety in Transportation.* The DOT Safety Council developed this definition after extensive review of definitions for safety culture used in a wide range of industries and organizations over the past two decades. FRA recognizes that railroads may have a slightly different understanding of what exactly makes up safety culture; however, for the purposes of this rule, FRA believes it is important to establish a shared definition of safety culture. Organizations with a strong safety culture will consistently choose safety over performance when faced with the choice of cutting corners to increase performance. Safety culture is discussed further in section-by-section analysis for § 270.101(b), which requires a railroad to design its SSP so that it promotes a positive safety culture.

"System safety" means the application of management, economic, and engineering principles and techniques to optimize all aspects of safety, within the constraints of operational effectiveness, time, and cost, throughout all phases of the system life cycle. By specifying that system safety operates within certain constraints, this definition clarifies that there may be hazards on the railroad's system that a railroad may not be capable of fully mitigating or eliminating, or where the costs to address the hazard are not commensurate with the risks. Rather, the railroad would monitor the hazard and at some point, if feasible, employ methods to mitigate or eliminate that hazard and resulting risk.

"System safety program" means a comprehensive process for the application management and engineering principles and techniques to optimize all aspects of safety. A railroad's SSP sets out how the railroad will implement system safety in its operations. Because this part describes specific requirements of a system safety program, this definition is intended to be high-level.

"System safety program plan" means a document developed by the railroad that implements and supports the railroad's SSP. Section 270.103 sets forth the specific requirements of a SSP plan.

"Tourist, scenic, historic, or excursion operations" means railroad operations that carry passengers, often using antiquated equipment, with the conveyance of the passengers to a particular destination not being the principal purpose. Train movements of new passenger equipment for demonstration purposes are not tourist, scenic, historic, or excursion operations. This definition is consistent with FRA's other regulations concerning passenger operations. *See* 49 CFR 238.5 and 239.5.

The NPRM proposed a waiver process in § 270.7 in which a railroad could request a waiver from a provision of the SSP rule. FRA determined that such a provision is unnecessary because the rules governing the FRA waiver process are already set forth in 49 CFR part 211. Therefore, a waiver provision has not been included in the SSP final rule.

Section 270.7 Penalties and Responsibility for Compliance

This section, originally proposed as § 270.9, contains provisions regarding the penalties for failure to comply with the rule and the responsibility for compliance. It is adopted and remains unchanged from the NPRM.

As explained in the NPRM, paragraph (a) identifies the civil penalties that FRA may impose upon any person that violates or causes a violation of any requirement of this part. These penalties are authorized by 49 U.S.C. 20156(h), 21301, 21302, and 21304. The penalty provision parallels penalty provisions included in numerous other safety regulations issued by FRA. In general, any person who violates any requirement of this part or causes the violation of any such requirement is subject to a civil penalty of at least $839 and not more than $27,455 per violation. Civil penalties may be assessed against individuals only for willful violations. Where a grossly negligent violation or a pattern of repeated violations creates an imminent hazard of death or injury to persons, or causes death or injury, a penalty not to exceed $109,819 per violation may be assessed. In addition, each day a violation continues constitutes a separate offense. Maximum penalties of $27,455 and $109,819 are required by the Federal Civil Penalties Inflation Adjustment Act of 1990, Public Law 101–410, 28 U.S.C. 2461, note, as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Public Law 114–74, Sec. 701. Furthermore, a person may be subject to criminal penalties under 49 U.S.C. 21311 for knowingly and willfully falsifying reports required by these regulations. FRA believes that the inclusion of penalty provisions for failure to comply with the regulations is important in ensuring that compliance is achieved. This final rule includes a schedule of civil penalties as Appendix A to this part. Because a penalty schedule is a statement of agency policy, notice and comment was not required before its issuance. *See* 5 U.S.C. 553(b)(3)(A).

Paragraph (b) clarifies that the requirements in the rule are applicable to any person (as defined in the rule) that performs any function or task required by the rule. Although various sections of the rule address the duties of passenger railroads, FRA intends that any person who performs any action on behalf of a passenger railroad or any person who performs any action covered by the rule is required to perform that action in the same manner as required of the passenger railroad, or be subject to FRA enforcement action. For example, if a passenger railroad contracts with another entity to perform duties covered by this rule, that entity is required to perform those duties in the same manner as the passenger railroad. While the passenger railroad remains responsible for complying with the rule, FRA can take enforcement action any person who performs any action on behalf of a passenger railroad or any person who performs any action covered by the rule.

Subpart B—System Safety Program Requirements

Section 270.101 System Safety Program: General

This section sets forth the general requirements of the rule and remains unchanged from the NPRM. Each railroad subject to this part (*i.e.*, each passenger railroad) is required to establish and fully implement a SSP that systematically evaluates railroad safety hazards on its system and manages the resulting risks to reduce the number and rates of railroad accidents, incidents, injuries, and fatalities. The main components of a railroad's SSP will be the risk-based hazard management program and risk-based hazard analysis that will be designed to proactively identify hazards and mitigate or eliminate the resulting risks from those hazards. The risk-based hazard management program and risk-based hazard analysis requirements are set forth in § 270.103(p) and (q).

To properly implement a SSP, a railroad is required to set forth a SSP plan pursuant to § 270.103. The SSP plan will be a document or a series/collection of documents that contain all of the elements required by this part and shall be designed to support the railroad's SSP.

Paragraph (b) requires that a railroad's SSP be designed so that it promotes a positive safety culture. Safety culture, as defined in § 270.5, is the shared values, actions and behaviors that demonstrate commitment to safety over competing goals and demands. U.S. DOT, Safety Council Research Paper, *SAFETY CULTURE: A Significant Driver Affecting Safety in Transportation* (May 2011). Research has shown that when an organization has a strong safety culture, accidents and incidents are less frequent and less severe. *Id.* at 4. Conversely, if an organization's safety culture is weak, significant and catastrophic accidents are more likely to occur. *Id.* For a railroad to achieve its SSP goals, the mitigation or elimination of safety hazards and risks on the rail system, the railroad must have a positive and strong safety culture, so it is vital that the railroad's SSP be designed so that it promotes a positive safety culture. Consistent with the Safety Council Research Paper, FRA believes that there are 10 elements that support a strong safety culture on a railroad. *Id.* at 7. These elements are: (1) Having leadership that is clearly committed to safety; (2) practicing continuous learning; (3) making decisions that demonstrate that safety is prioritized over competing demands; (4) having clearly defined reporting systems and accountability; (5) promoting a safety-conscious work environment; (6) making employees feel personally responsible for safety; (7) fostering open and effective communication across the railroad; (8) fostering mutual trust between employees and the railroad; (9) responding to safety concerns in a fair and consistent manner; and (10) having training and other resources available to support safety. *Id.* at 7–8. While these 10 elements are not requirements of this rule, FRA believes that if a railroad incorporates each element, the railroad will have a strong safety culture. Further, implementing these elements will provide the railroad the necessary framework to effectively describe its safety culture as required by § 270.103(b)(2) and describe how it measures the success of its safety culture as required § 270.103(t).

Section 270.103 System Safety Program Plan

This section implements a railroad's SSP through a SSP plan. This section received numerous comments and these comments are addressed in the appropriate subsection to which they refer. As mentioned previously, a railroad is required to create a written SSP plan to fully implement and support its SSP. This section sets forth all of the required elements of the railroad's SSP plan.

Paragraph (a) establishes that a railroad's SSP plan must contain the minimum elements set forth in this section. FRA did not receive any comments regarding paragraph (a) and therefore it remains unchanged from the NPRM. As provided in § 270.201, a railroad's SSP plan must be submitted to and approved by the FRA Associate Administrator for Railroad Safety and Chief Safety Officer. FRA Associate Administrator for Railroad Safety and Chief Safety Officer approval of the SSP plan will be considered approval of the railroad's SSP as required by section 20156(a)(3).

In certain scenarios, a railroad providing passenger service is not the railroad that owns the track on which passenger service is being operated. Rather, the railroad that owns the track hosts the railroad providing the passenger train service. For a railroad providing passenger train service to effectively identify, evaluate, and manage the hazards and resulting risks on the system over which it operates, as required by this part, the railroad needs to evaluate all aspects of the operation. As such, paragraph (a)(2) of this section addresses the coordination that must occur between a railroad providing passenger service and a railroad hosting that passenger service. If certain aspects of the operation are not under the control of the railroad providing passenger service but are controlled by the railroad hosting the operation, the two railroads need to communicate so those aspects can be adequately addressed by the railroad's SSP. A passenger railroad may have multiple railroads hosting its passenger train service on its system and therefore needs to coordinate with each railroad. If a railroad hosting the passenger train service does not cooperate with the railroad providing the passenger train service to coordinate the applicable parts of the SSP, under § 270.7, the railroad hosting the passenger train service may be subject to civil penalties because it may cause the railroad providing the passenger service to violate the requirements of this part. For example, if a passenger railroad service is hosted by a freight railroad and that freight railroad is responsible for track maintenance, the freight railroad will need to provide the passenger railroad the necessary information regarding track maintenance for the passenger railroad to prepare its SSP plan. Since track maintenance has significant impact on the safety of rail operations, it is a vital element of a railroad's SSP plan. Therefore, if the freight railroad refuses to provide the passenger railroad the necessary information regarding track maintenance, the passenger railroad will not be able to fully comply with this part and, consequently, the freight railroad may be subject to civil penalties for causing the passenger railroad to fail to comply with this part.

APTA requested that FRA address coordination issues whereby one railroad can adopt and operate under another railroad's SSP plan. There is nothing in this rule prohibiting a railroad's SSP plan from adopting certain portions of another railroad's SSP plan if those portions cover the same operations on both railroads. However, no two railroad operations are exactly the same; therefore, no two SSP plans will be exactly the same. If a railroad adopts portions of another railroad's plan, the operations covered by those portions of the plan must involve the same directly affected employees and both railroads must independently comply with the consultation requirements under this rule.

APTA also requested that FRA allow railroads to develop SSP plans for a jointly served facility and allow properties with multiple host railroads to have SSP plans specific to each of the territories that a host railroad supports. There is nothing in the rule prohibiting railroads from jointly developing portions of their SSP plans; however, the railroads must ensure that the jointly developed portions address all the necessary requirements of this rule. Each railroad can include the jointly developed portions in their plans, but each portion must involve the same directly affected employees and both railroads must independently comply with the consultation requirements under this rule.

Paragraph (b) requires each SSP plan to have a policy statement that endorses the railroad's SSP. It should be noted that proposed paragraph (c)(1) has been moved to paragraph (b). The policy statement required by this paragraph should define, as clearly as possible, the railroad's authority for the establishment and implementation of the SSP. This includes the legal name of the entity responsible for developing the railroad, any authorizing or implementing legislation, and federal, state & local statutes enacted to establish the railroad.

The policy statement is required to be signed by the chief official of the railroad. This signature would indicate that the top level of management at the railroad endorses the railroad's SSP. AAR requested that the chief official for safety should be required to sign the system safety program, not the chief official at the railroad. AAR believes that the title of "chief official at the railroad" is ambiguous because railroads have different organizational structures and there may not be one person with the title of "chief official." AAR claims that FRA has departed from the language in the statutory mandate which requires the chief official for safety to sign the SSP plan. AAR also believes that the chief official for safety is the more appropriate person to sign the SSP plan because he/she will be more familiar with the details of the SSP than the other senior railroad officials and the chief official for safety will be directly responsible for the preparation of the SSP plan. FRA does not disagree that the chief official for safety should be required to sign the SSP plan. Indeed, the chief official for safety is not only required by this rule to sign the SSP plan but is required to certify that the contents of the SSP plan are accurate and that the railroad will implement the contents of the plan. *See* 49 CFR 270.201(a)(3)(i). FRA is not deviating from the requirements in the statutory mandate. Section 270.201(a)(3)(i) virtually mirrors the language in section 20156(b). AAR has mistaken § 270.103(b) as requiring the chief official at the railroad to sign the SSP plan. This paragraph requires the chief official at the railroad only to sign the SSP policy statement, not the entire SSP plan. Prior experience with effective risk management programs has demonstrated to FRA the importance of the active involvement of the highest officials in improving safety and safety culture. For this reason, FRA has determined that the chief official at the railroad must sign the SSP policy statement.

FRA notes that this policy statement is also required to describe the safety philosophy and culture of the railroad. Section 270.101(b) requires a railroad to design its SSP so that it promotes and supports a positive safety culture as defined by § 270.5. In order for a railroad to properly design its SSP so that it promotes and supports a positive safety culture, it first needs to describe its safety culture and philosophy. As discussed previously, FRA believes that there are 10 elements that are critical to a strong safety culture and these 10 elements provide the necessary framework for a railroad to comprehensively describe its safety culture. Once its safety culture is described, the railroad must also describe how it measures the success of its safety culture pursuant to paragraph (t) of this section. The requirement for this description was proposed in § 270.103(c)(1) of the NPRM; however, as discussed in the next paragraph, FRA has determined to delete proposed § 270.103(c).

As proposed in the NPRM, paragraph (c) would have required a railroad to set forth a statement in its SSP plan that describes the purpose and scope of the railroad's SSP. The statement would have been required to have, at a minimum, three elements. However, upon further consideration, FRA has determined that these three elements are better placed elsewhere in the rule. Therefore, proposed § 270.103(c), Purpose and scope of system safety program, has been removed. As noted above, proposed § 270.103(c)(1) has been moved to § 270.103(b), System safety program policy statement, and proposed § 270.103(c)(2) and (3) have been moved to § 270.103(e), Railroad management and organizational structure, which was proposed as § 270.103(f) in the NPRM. FRA believes by moving these sections, the requirements are clearer and more consistent.

Paragraph (c) of the final rule, proposed as paragraph (d) in the NPRM, addresses the importance of goals in a SSP. The central goal of a SSP is to manage or eliminate hazards and the resulting risks to reduce the number and rates of railroad accidents, incidents, injuries, and fatalities. FRA believes one way to achieve this central goal is for a railroad to set forth goals that are designed in such a way that when the railroad achieves these goals, the central goal is achieved as well. The APTA System Safety Manual served as the model for the guidelines set forth in paragraph (c).

Paragraph (c) requires a railroad to include as part of its SSP plan a statement that defines the goals for its SSP. The statement must describe the clear strategies on how the railroad will achieve these goals. These strategies will be the railroad's opportunity to provide its vision on how these particular goals will ultimately reduce the number and rates of railroad accidents, incidents, injuries and fatalities. The statement must also describe what the railroad's management's responsibilities are to achieve the system safety goals. This statement will make it clear to the railroad, railroad employees, and FRA who, and at what level within management, is responsible for ensuring that the stated goals are achieved.

Rather than setting forth specific requirements that these goals must satisfy, paragraph (c) contains general requirements. This allows railroads the flexibility to establish goals specific to their operations. The general parameters of these goals are that they should be—

- long-term, so that they are relevant to the railroad's SSP. This does not mean that goals cannot have relevance in the short-term. Rather, goals must have significance beyond the short-term and continue to contribute to the SSP. The NPRM proposed that the goals should be relevant to the railroad "throughout the foreseeable life of the railroad." FRA determined to delete the quoted language to reduce any confusion;
- meaningful, so that they are not so broad that they cannot be attributed to specific aspects of the railroad's operations. The desired results must be specific and must have a meaningful impact on safety;
- measurable, so that they are designed in such a way that it is easily determined whether each goal is achieved or at least progress is being made to achieve the goal; and
- consistent with the overall goal(s) of the SSP, in that they must be focused on the identification of hazards and the elimination or mitigation of the resulting risks.

FRA notes that the NY MTA, in commenting on the NPRM, believes it is critical that FRA and OSHA align their positions related to numerical goals. NY MTA states that OSHA has indicated that simply setting numerical safety goals discourages accident reporting and that the goal of a SSP as described in the NPRM appears to be focused on setting such numerical goals. NY MTA is concerned that any conflict between OSHA's perspective and the main goal of a SSP program could have the unattended effect of hampering safety programs.

FRA agrees with NY MTA that the goals of a SSP cannot be focused exclusively on numerical values, *e.g.*, accident rates, employee injury rates, etc.; however, FRA believes that paragraph (c), like the SSP rule as a whole, does not focus solely on numerical goals. While the central goal of a SSP is to manage risks to reduce the number and rates of railroad accidents, incidents, injuries, and fatalities, this is not the sole goal of a SSP. A SSP must be designed and implemented so that it systematically reduces hazards and the resulting risks on a railroad's system. This rule provides each railroad with the flexibility to adapt a SSP to its system—the rule is not focused on a rigid numerical goal. A properly implemented SSP should naturally result in reduced rates of railroad accidents, incidents, injuries, and fatalities.

Paragraph (d), proposed as paragraph (e) in the NPRM, requires a railroad to set forth a statement in its SSP plan describing the characteristics of the railroad's system. FRA received comments from AAR, Labor Organizations, and the NY MTA regarding this paragraph. The railroad's system description is an important part of the overall SSP. This is the section where the railroad will provide sufficient information to allow a basic understanding of the railroad and its operations. A good system description is important to understand the operating environment and interfaces that occur during operation of passenger trains, especially those elements that may positively or negatively affect safety. If the system is not described accurately, then the risk-based hazard analysis and resulting mitigations may be flawed.

Understanding the breadth of the railroad system is also fundamentally necessary for FRA to be able to review and audit a railroad's SSP. This description will allow FRA to determine whether the railroad's program sufficiently covers the railroad's operations and the extent of the risks/hazards on its system. The description will also focus the railroad on its staff and contractors that have an effect on the safety of its operations and, therefore, have an effect on the success of its SSP.

This information is required for FRA to understand the extent of infrastructure and operations so that they can relate the safety aspects of the plan to the railroad specifically. When carrying out enforcement action such as reviewing annual assessments or performing audits, FRA will have a basis of understanding for what, where and who is responsible. This is a key input in order to establish a ''baseline'' of a railroad's safety environment and culture.

FRA notes that passenger railroads often answer to officials representing governmental jurisdictions served by those railroads. FRA believes a SSP plan will be ineffective if those officials cannot easily be made aware of the nature of the railroads' operations and how those operations are made safer through the SSPs. FRA believes that for the SSPs required by RSIA to be effective, this information must be readily available to relevant governmental officials. Further, this information will make it easier for those governmental officials to inform railroads of, or place emphasis upon, relevant hazards, improving the quality of the SSPs. For example, States have safety rail inspectors who work in collaboration with FRA, to which that information will be useful. Railroads for the most part have this information currently; it's simply a matter of inserting into the plan document.

Generally, the description of the characteristics of the railroad's system should be sufficient to allow persons who are not familiar with the railroad's operations and railroad operations in general to understand the railroad's system and its basic operations. Specifically, this statement describes the following:

- The railroad's operations (including any host operations), including the role, responsibilities, and organization of the railroad's operating departments.
- The physical characteristics of the railroad, including the number miles of track over which the railroad operates, the number of stations the railroad services, the number and types of grade crossings over which the railroad operates, on which segments the railroad shares track with other railroads, the maximum authorized speed, and toxic inhalation hazard routing.
- The scope of the service the railroad provides, including the number of passengers, the number of routes, and the days and hours when service is provided. The railroad may also provide a system map.
- The maintenance activities performed by the railroad, including the role, responsibilities, and organization of the railroad's various maintenance departments and the type of maintenance required by the railroad's operations and facilities.
- Any other aspects of the railroad pertinent to the railroad's operations.

The NPRM proposed requiring a description of the history of the railroad's operations and physical plant. FRA determined that these descriptions were not necessary because any pertinent information they would provide is already addressed by the other descriptions required by paragraph (d)(1).

Paragraph (d)(2) requires a railroad to identify in its SSP plan certain persons that provide or utilize significant safety-related services. The railroad will identify persons that have entered into a contractual relationship with the railroad to either perform significant safety-related services on the railroad's behalf or to utilize significant safety-related services provided by the railroad for purposes related to railroad operations. The term ''significant safety-related services'' is intended to be understood broadly to give a railroad the flexibility to evaluate the services other entities provide to the railroad and the degree that these services are safety-related. FRA has edited this section from the NPRM to clarify who needs to be identified by the railroad. First, the NPRM proposed that a railroad identify ''entities or persons that provide significant safety-related services.'' However, FRA determined that the term ''entities'' was redundant because the definition for ''person'' in § 270.5 covers all of the entities that would need to be identified, therefore, the term ''entities'' has been removed. Second, the proposed rule text in the NPRM did not include the requirement that the person must be providing the services on the railroad's behalf. This was added to clarify the relationship between the railroad and the person providing the service. The contractual basis of this relationship is discussed further in this section.

Third, the proposed rule text in the NPRM did not include the requirement that the railroad describe the persons that utilize significant safety-related services of the railroad; however, the NPRM did request comment on whether FRA should add this requirement. FRA received comments from AAR, APTA, Labor Organizations, and NY MTA in response to this request. AAR was unsure of which persons FRA meant when referring to persons that utilize significant safety-related services and suggested that the railroad itself could be a person that utilizes significant safety-related services. APTA commented that general considerations can be given for customers, motorists using highway rail-grade crossings and communities served by safe alternative transportation. However, APTA believes that there is no useful purpose for including this requirement in the rule. FRA has added the requirement that the railroad identify persons that utilize significant safety-related services, but included language to clarify which persons would fall under this category. The railroad will identify persons that utilize significant safety-related services provided by the railroad for the purpose related to railroad operations. For example, if a railroad contracts with a company to perform bridge maintenance, that company provides a significant safety-related service to the railroad on behalf of the railroad and would be identified as so under this paragraph. If during the bridge maintenance, the company uses the railroad's roadway worker protection, that company is then utilizing a significant safety-related service (roadway worker protection) provided by the railroad and would be identified as so under this paragraph. A railroad does not have to identify persons providing or utilizing significant safety-related services for purposes unrelated to railroad operations, such as railroad passengers or motor vehicle drivers who benefit from a highway-rail grade crossing warning system.

Fourth, FRA has added a contractual element to the relationship between the railroad and persons that provide or utilize significant safety-related services. This was added to ensure that there is a formalized agreement between the railroad and the person regarding the service that is provided or utilized. With the formalized agreement, the duties of the contractor would be clear and, therefore, the extent they are performing or utilizing significant safety-related services of the railroad would be clear as well. FRA would give a railroad significant discretion to identify which persons utilize or provide significant safety-related services. In interpreting this proposed provision, emphasis would be placed upon the words "significant" and "safety-related." FRA does not expect a railroad to identify every person that provides it services. For example, a railroad would be expected to identify a signal contractor that routinely performed services on its behalf, but not a contractor hired on a one-time basis to pave a grade crossing. If a railroad was uncertain whether a person should be identified, it would be encouraged to contact FRA for further guidance. Generally, however, this section would require identification of those persons whose significant safety-related services or utilization would be affected by the railroad's SSP. FRA recognizes that not all railroad operations are the same; thus, not all persons that utilize or provide significant safety-related services will be the same. During its review of a railroad's SSP plan, FRA will determine whether the persons the railroad has sufficiently described significant safety-related services and identified the proper persons.

NY MTA recommended that FRA permit railroads to use the same safety-related matrix for designating employees that was proposed in the Training Standards NPRM to identify persons that provide significant safety-related services. NY MTA believes this will be more practical for staff changes, while still establishing accountability. On November 7, 2014, FRA published in the **Federal Register** a Final Rule entitled "Training, Qualification, and Oversight for Safety-Related Railroad Employees." 79 FR 66460. Generally, the Training Standards Rule requires each railroad or contractor that employs one or more "safety-related railroad employee" as defined by § 243.5, to develop and submit a training program to FRA for approval and to designate the minimum qualifications for each occupational category of employee. *Id.* The Training Standards Rule defines "safety-related railroad employee" as follows:

> *Safety-related railroad employee* means an individual who is engaged or compensated by an employer to: (1) Perform work covered under the hours of service laws found at 49 U.S.C. 21101, *et seq.;* (2) Perform work as an operating railroad employee who is not subject to the hours of service laws found at 49 U.S.C. 21101, *et seq.;* (3) In the application of parts 213 and 214 of this chapter, inspect, install, repair, or maintain track, roadbed, and signal and communication systems, including a roadway worker or railroad bridge worker as defined in § 214.7 of this chapter; (4) Inspect, repair, or maintain locomotives, passenger cars or freight cars; (5) Inspect, repair, or maintain other railroad on-track equipment when such equipment is in a service that constitutes a train movement under part 232 of this chapter; (6) Determine that an on-track roadway maintenance machine or hi-rail vehicle may be used in accordance with part 214, subpart D of this chapter, without repair of a non-complying condition; (7) Directly instruct, mentor, inspect, or test, as a primary duty, any person while that other person is engaged in a safety-related task; or (8) Directly supervise the performance of safety-related duties in connection with periodic oversight in accordance with § 243.205.

79 FR 66502.

Pursuant to § 243.101(c), the railroad is required to provide a table or other suitable format that lists, among other things, the railroad's safety-related employees. 49 CFR 243.101(c). While the matrix required by the Training Standards rule may provide the railroads with guidance regarding which persons provide significant safety-related services, it is not clear whether the matrix would cover persons that utilize significant safety-related services. Therefore, FRA declines to adopt NY MTA's suggestion.

The Labor Organizations expressed concern that railroads may contract out the majority of their safety-related services or allow a third party to perform such services to evade their statutory obligations under this part. The Labor Organizations believe that simply requiring identification of the persons that a railroad may or may not use for safety-related services would make it very difficult for FRA to determine whether the railroads are complying with this part. To avoid such difficulty, the Labor Organizations request that FRA make clear that the responsibility for compliance with this rule is non-delegable. Pursuant to §§ 270.3 and 270.7, as explained above in the accompanying section-by-section analysis, the railroad is ultimately responsible for compliance with this final rule and cannot delegate this duty. Section 270.7(b) provides that a railroad may contract with another person to perform the duties under this rule; however, that person is required to perform these duties in the same manner as the railroad and is subject to FRA enforcement action. The railroad remains accountable even if it does contract with another person to perform the duties required by this rule. Of course, the other person must perform the required duties in compliance with this rule, and both the railroad and the contracted person are subject to FRA enforcement action.

Finally, an individual also commented that it is important to ensure that persons providing significant safety-related services are qualified or credentialed, or both, to provide such services. FRA believes such a requirement is unnecessary because persons that perform any duty on behalf of the railroad are required to perform these duties consistent with this regulation and any other applicable safety laws and regulations. Therefore, a railroad is required to ensure that any person that provides significant safety-related services do so consistent with this regulation and any other applicable safety laws and regulations.

Paragraph (d)(3) incorporates text from proposed paragraph (f)(4) of the NPRM. FRA determined that the requirements in proposed paragraph (f)(4) were better placed in paragraph (d) because the requirements are part of the railroad system description. Paragraph (d)(3) requires the railroad to describe the relationship and responsibilities between it and certain other persons. These persons include any host railroads, contract operators, shared track/corridor operators, and other persons that utilize or provide significant safety-related services as identified by the railroad in paragraph (d)(2) of this section. Describing the relationship and responsibilities between the railroad and any host railroads, contract operators, or shared track/corridor operators should be relatively straight forward because a railroad most likely has entered into contracts or memoranda of agreement with these persons that outline this information. The description should be detailed enough so that FRA can understand the basis of the relationship and the responsibilities of each person based on that relationship. For example a commuter railroad may contract out operation of the commuter trains to one corporation and contract out track maintenance on the commuter railroad's own trackage to another corporation. For a certain section of the route, the commuter railroad's trains are hosted by another railroad on the other railroad's tracks and that other railroad provides the dispatching and signal/track maintenance for that portion of track. The commuter railroad would need to outline these relationships and responsibilities in the plan. Not only to ensure that FRA understands, but also to ensure the railroad has a complete understanding of who performs the various activities. Many departments know who and what they do and contract out, but do not have a grasp of the big picture for the entire commuter railroad.

Paragraph (e), proposed as paragraph (f) in the NPRM, requires a railroad to set forth a statement in its SSP plan that describes the management and organizational structure of the railroad. RSIA requires a railroad's hazard analysis to identify and analyze the railroad's management structure. 49 U.S.C. 20156(c). Under this section, the railroad will identify its management structure and how safety responsibilities are distributed throughout the railroad.

As discussed previously, to maintain consistency and increase clarity, proposed paragraphs (c)(2) and (3) have been incorporated into paragraph (e) of this section. The statement pursuant to paragraph (e) shall include a chart or other visual representation of the organizational structure of the railroad; description of the railroad's management responsibilities within the SSP; description of how the safety responsibilities are distributed within the railroad organization; clear identification of the lines of authority used by the railroad to manage safety issues; and a description of the roles and responsibilities in the railroad's system safety program for each host railroad, contract operator, shared track/corridor operator, and other person that utilizes or provides significant safety-related services as identified by the railroad pursuant to (d)(2) of this section. The statement shall also describe how each host railroad, contractor operator, shared track/corridor operator, and any other person that utilizes or provides significant safety-related services as identified by the railroad pursuant to paragraph (d)(2) of this section supports and participates in the railroad's system safety program, as appropriate. Under paragraph (e)(1), the chart or other visual representation of the organizational structure of the railroad does not need to be overly detailed. Rather, it must identify the divisions within the railroad, the key management positions within each division, and titles of the officials in those positions.

Under paragraph (e)(2), the railroad shall describe the railroad's management's responsibilities within the SSP. This description clarifies who within the railroad's management are responsible for which aspects of the SSP.

Under paragraph (e)(3), a railroad must identify how the safety responsibilities are distributed within the railroad's departments. A railroad may have one department that handles safety matters or there may be multiple departments and each department has separate and distinct responsibilities for handling safety matters. Regardless of how the railroad distributes the overall responsibility to manage safety issues, it is important that the railroad identifies and describes how safety is being managed on its system.

Under paragraph (e)(4), the railroad also needs to clearly identify which of the management positions within the department(s) are responsible for managing the safety issues within the railroad. Identification of these lines of authority allows FRA to determine who within the organization and at what level has responsibility for managing the safety issues. While FRA recognizes that safety is everybody's responsibility within the railroad organization, the management personnel responsible for managing the safety issues need to be identified.

Paragraph (e)(5) requires the railroad to describe the roles and responsibilities in the railroad's SSP for each host railroad, contract operator, shared track/corridor operator, and any other person that utilizes or provides significant safety-related services. Since these persons play a key role in the safe operation of the railroad, their role and responsibilities in the railroad's SSP must be described.

Paragraph (e)(5) also requires the railroad to describe how each host railroad, contractor, shared track/corridor operator, and any other person that utilizes or provides significant safety-related services as identified by the railroad pursuant to paragraph (d)(2) supports and participates in the railroad's SSP, as appropriate.

Paragraph (f), proposed as paragraph (g) in the NPRM, requires a railroad's SSP plan to include a description of the process the railroad will use to implement its SSP. RSIA requires passenger railroads to implement a SSP plan that is approved by the Secretary. 49 U.S.C. 20156(a)(1)(C). Under this section, the railroad will describe how it will implement its SSP, which will allow FRA, during initial plan approval and subsequent audits, to determine if the railroad is properly implementing its SSP.

The implementation process must, at a minimum, address the roles and responsibilities of each position (including those held by employees, contractors, and other persons that utilize or provide significant safety-related services) that has significant responsibilities to implement the SSP. The addition of persons that utilize significant safety-related services is consistent with the discussion in paragraph (d)(2). The NPRM proposed that the statement would address the roles and responsibilities of each position and job function that has significant responsibilities to implement the SSP. FRA determined that the term "job function" was redundant; therefore, all references in the rule have been removed. The process must also identify the milestones necessary to be reached to properly implement the SSP. FRA did not receive any comments in response to paragraph (f); however, as discussed in the next paragraph, FRA has included the requirement in paragraph (f) that the SSP be fully implemented within 36 months of FRA approval. Further, in the NPRM this paragraph proposed to require an implementation plan; however, FRA has determined that a description of the implementation process is more appropriate than requiring a formal plan.

FRA notes that in the NPRM there was no proposal for the railroad to specify a timeframe in which it would be required to fully implement, as defined in § 270.5, its SSP; however FRA believes such a timeline is necessary. FRA has determined that 36 months is a sufficient amount of time for a railroad to fully implement its SSP. With such a time frame, a railroad can effectively allocate the resources necessary to fully implement its SSP while also prioritizing the implementation of specific elements. Further, with this timeframe, the railroad will be able to more precisely set the milestones as required by this section. While "fully implemented" is defined in § 270.5, there are no rigid criteria that determine if a program is fully implemented. To determine if a program is fully implemented, FRA will consider the extent to which each section of the plan is implemented and the railroad, along with its stakeholders, are actively fulfilling each section. For example, regarding paragraph (c), System safety program goals, FRA will consider the extent to which a railroad has developed written goals that are long-term, meaningful, measurable, and focused on the identification of hazards and the mitigation or elimination of the resulting risks, and whether there are programs in place for the railroad to achieve the written goals.

The positions that will be described pursuant to paragraph (f) are those that are responsible for implementing the major elements of the SSP, to the extent that the individuals having these positions have clear and concrete roles and responsibilities. Not every individual who participates in the railroad's SSP needs to be described as part of the implementation process but rather only those individuals who have significant responsibilities for implementing the railroad's SSP. The phrase "significant responsibilities" is intended to be broadly defined to provide the railroads the flexibility to determine, based on their individual operations, what may be considered "significant responsibilities."

In its SSP plan a railroad will set forth the milestones to demonstrate that it has properly implemented its SSP. Each railroad's SSP will be different; therefore, the milestones that must be achieved to properly implement a SSP will be different. A railroad has the flexibility to determine, based on its own SSP and not rigid requirements, realistic benchmarks that need to be achieved to properly implement its SSP. FRA understands that there may be unforeseeable circumstances that can cause a railroad to adjust the implementation of its SSP and subsequently adjust these milestones. The important consideration is that the railroad sets forth milestones that can be used to determine the progress of the railroad's implementation of its SSP.

Paragraph (g), proposed paragraph (h) in the NPRM, addresses a railroad's maintenance and repair program. RSIA requires a railroad's hazard analysis to "identify and analyze" the railroad's "infrastructure" and "equipment." 49 U.S.C. 20156(c). Under this section, the railroad will identify its procedures and processes for the maintenance, repair, and inspection of such infrastructure and equipment. This identification is necessary for the railroad to conduct a thorough risk-based hazard analysis and will allow FRA, during initial plan review and subsequent audits, to determine if the railroad's SSP sufficiently addresses the risk and hazards generated by the railroad's infrastructure and equipment. FRA received three comments in response to this paragraph. Based on these comments, paragraph (g)(4) was added.

Paragraph (g)(1) requires a railroad's SSP plan to identify and describe the processes and procedures used for maintenance and repair of its infrastructure and equipment directly affecting railroad safety. The phrase "infrastructure and equipment directly affecting railroad safety" is intended to be broadly understood to provide the railroad the opportunity to take a realistic survey of its particular operations and make the determination of which infrastructure and equipment directly affect the safety of that railroad. However, as guidance, a list of the types of infrastructure and equipment that are considered to directly affect railroad safety is provided. This list includes: Fixed facilities and equipment, rolling stock, signal and train control systems, track and right-of-way, passenger train/station platform interface (gaps), and traction power distribution systems. The list in the NPRM did not include passenger train/station platform interface (gaps); however, FRA believes passenger train/station platform interface (gaps) are an important element of a railroad's infrastructure and will provide the railroad with further opportunities to identify hazards and the resulting risks and eliminate or mitigating these hazards. Once the railroad has determined what infrastructure and equipment directly affect railroad safety, it will then identify and describe the processes and procedures used for the maintenance and repair of that infrastructure and equipment. The safety of a railroad's operations depends greatly upon the condition of its infrastructure and equipment; therefore, these maintenance and repair processes and procedures should and are expected to already be in place.

Under paragraph (g)(2), each description of the processes and procedures used for maintenance and repair of infrastructure and equipment directly affecting safety must include the processes and procedures used to conduct testing and inspections of the infrastructure and equipment. Multiple FRA regulations require a railroad to conduct testing and inspection of infrastructure and equipment, and paragraph (g)(2) addresses the processes and procedures that the railroad has developed to meet these regulatory standards. For example, pursuant to 49 CFR part 234, a railroad must inspect, test, and repair warning systems at highway-rail grade crossings. Under paragraph (g)(2), the railroad will describe the internal procedures it has developed to conduct such inspections, tests, and repairs and how it educates its employees on the proper way to conduct the inspection, testing and repair of highway-rail grade crossing warning systems. As discussed below, in certain situations, paragraph (g)(3) permits referencing these manuals in the SSP plan rather than providing the entire manual.

Typically, railroads have a manual or manuals that describe the maintenance and testing procedures and processes used to conduct testing and inspections of the infrastructure and equipment. FRA has included paragraph (g)(3) to address the use of such manuals in a SSP plan. Rather than including an entire manual in its SSP plan, if the manual satisfies all applicable Federal regulations, in most cases simply referencing the manual in the SSP plan will satisfy this paragraph. If a manual does not comply with all applicable Federal regulations, it cannot be included in the plan. If any the regulations that apply to these are updated, the manuals and references to such will need to be updated as well. Approval of a SSP plan that references manuals that describe the maintenance and testing procedures and processes used to conduct testing and inspections of the infrastructure and equipment does not necessarily mean that the manuals satisfy all applicable regulations. Rather, each manual must independently comply with the applicable regulations and is subject to a civil penalty if not in compliance. If FRA finds it necessary to review the manuals, FRA will examine whether the manuals are current, if they are readily available to the employees who are performing the functions the manuals address, and if these employees have been trained on their use.

While FRA is always concerned with the safety of railroad employees performing their duties, employee safety in maintenance and servicing areas generally falls within the jurisdiction of OSHA. It is not FRA's intent in this rule to displace OSHA's jurisdiction regarding the safety of employees while performing inspections, tests, and maintenance, except where FRA has already addressed workplace safety issues, such as blue signal protection in 49 CFR part 218. In other rules, FRA has included a provision that makes it clear that FRA does not intend to displace OSHA's jurisdiction over certain subject matters. *See, e.g.,* 49 CFR 238.107(c).

In the NPRM, FRA sought comment on whether such a clarifying statement was necessary for any such subject matter that the proposed rule may affect. APTA, the Labor Organizations, and an individual commenter all provided comments in response to this request. All of the commenters agree that the final rule should contain such a clarifying statement; therefore, paragraph (g)(4) has been included in this section. Modeled after 49 CFR 238.107(c), paragraph (g)(4) makes clear that FRA neither intends to displace OSHA jurisdiction with respect to employee working conditions generally nor specifically with respect to the maintenance, repair, and inspection of infrastructure and equipment directly affecting railroad safety. FRA does not intend to approve any specific portion of a SSP plan that relates exclusively to employee working conditions covered by OSHA. The term "approve" is used to make it clear that any part of a plan that relates to employee working conditions exclusively covered by OSHA will not be approved even if the overall plan is approved. Additionally, the term "specific" reinforces that the particular portion of the plan that relates to employee working conditions exclusively covered by OSHA will not be approved; however, the rest of the plan may still be approved. As discussed below, paragraph (g)(4) also applies to paragraph (k) regarding OSHA jurisdiction over any workplace safety programs. If there is any confusion regarding whether a plan covers an OSHA-regulated area, FRA is available to provide assistance.

Paragraph (h), proposed as paragraph (i) in the NPRM, requires a railroad's SSP plan to set forth a statement describing the railroad's processes and procedures for developing, maintaining, and ensuring compliance with the railroad's rules and procedures directly affecting railroad safety and the railroad's processes for complying with applicable railroad safety laws and regulations. RSIA requires a railroad's hazard analysis to identify and analyze the railroad's operating rules and practices. 49 U.S.C. 20156(c). Under this paragraph, the railroad will identify the railroad's operating rules and practices. FRA did not receive any comments in response to this paragraph as proposed in the NPRM; however, the term "maintenance" has been included in paragraph (h)(1) to be consistent with paragraph (h)(3). This statement describes how the railroad not only develops, maintains, and complies with its own safety rules, but also how the railroad complies with applicable railroad safety laws and regulations. The statement includes identification of the railroad's operating and safety rules and procedures that are subject to review under chapter II, subtitle B of title 49 of the Code of Federal Regulations, *i.e.,* all of FRA's railroad safety regulations.

The railroad must also identify the techniques used to assess the compliance of its employees with applicable railroad safety laws and regulations and the railroad's operating and safety rules and maintenance procedures. Both Federal railroad safety laws and regulations and railroad operating and safety rules and maintenance procedures are effective at increasing the safety of the railroad's operations only if the railroad and its employees comply with such rules and procedures. By ensuring compliance with such rules and procedures, the overall safety of the railroad is improved. The NPRM proposed requiring that the railroad identify the techniques to assess compliance of the railroad's employees with "applicable FRA regulations"; however, to be consistent with the other requirements in paragraph (h), FRA has revised this language to "railroad safety laws and regulations."

The railroad must identify the techniques used to assess the effectiveness of the railroad's supervision relating to compliance with applicable railroad safety laws and regulations and the railroad's operating and safety rules and maintenance procedures. If the railroad's supervision relating to compliance with these rules and procedures is effective, the employees' compliance should also be effective, thus improving the overall safety of the railroad.

Paragraph (i), proposed as paragraph (j) in the NPRM, requires each railroad to train necessary personnel on in its SSP plan. As proposed, paragraph (i) did not have the explicit requirement that the railroad train the necessary employees; thus, paragraph (i)(1) has been added to make this clear. Paragraph (i) also requires that each railroad establish and describe its plan how the necessary personnel will be trained on the SSP. As proposed in the NPRM, paragraph (i) did not require a railroad to establish a plan addressing how its employees will be trained on the SSP. Since some railroads will not have a SSP in place before the effective date of this final rule, FRA determined that it was necessary to include the requirement that a railroad not only describe but also establish a plan addressing how its employees will be trained on the SSP. This ensures that a railroad has such a plan in place and that it can be properly described pursuant to this paragraph.

The SSP training plan will describe the procedures in which employees that are responsible for implementing and supporting the program and any other person that utilizes or provides significant safety-related services will be trained on the railroad's SSP. The NPRM proposed that "contractors who provide significant safety-related services" needed to be trained as well. However, FRA determined that the phrase "persons utilizing or performing significant safety-related services" includes contractors who provide significant safety-related services; therefore, the phrase "contractors who provide significant safety-related services" has been removed. A railroad's SSP can be successful only if those who are responsible for implementing and supporting the program understand the requirements and goals of the program. To this end, a railroad would train those responsible for implementing and supporting the railroad's SSP on the elements of the program so that they have the knowledge and skills to fulfill their responsibilities under the program.

For each position or job title that has been identified under paragraph (f)(1)(i) as having significant responsibility for implementing a railroad's SSP, the railroad's training plan must describe the frequency and the content of the training on the SSP that the position or job title receives. If the railroad does not identify a position or job title under paragraph (f)(1)(i) as having significant responsibility to implement the SSP but the position or job title is safety-related or has a significant impact on safety, personnel in these positions will be required to receive basic training on the system safety concepts and the system safety implications of their position. Even though the personnel may not have responsibilities to implement the railroad's SSP, they do have an impact on the program because their position is safety-related or has a significant impact on safety, or both. It is important that all persons who may have an impact on the success of a railroad's SSP understand the requirements of the program so they can work together to achieve its goals.

Paragraph (i)(5) provides that a railroad may conduct its SSP training by classroom, computer-based, or correspondence training. Paragraph (i) is not intended to limit the forms of training; rather, it provides the railroads the flexibility to conduct training using methods other than traditional classroom training. SSP training may also be combined with a railroad's regular safety or rules training and in some cases SSP training could be included in field "tool box" safety training sessions. APTA requested that FRA make it clear in the rule text that the methods listed in paragraph (i)(4) were illustrative and not restrictive. FRA has revised the text of paragraph (i)(4) to address this concern. Additionally, for clarity and consistency with 49 CFR part 243, the methods listed are "classroom, computer-based, or correspondence training," which differs slightly from the NPRM; however, as discussed, the list is only illustrative and not restrictive.

Paragraph (i)(6) requires each railroad to keep a record of all training conducted under paragraph (i) and describe the process it will use to maintain and update these training records. The requirement that the railroad keep a record of all training was originally proposed in paragraph (i)(1); however, FRA believes it is more consistent to include it in paragraph (i)(6). Paragraph (i)(7) requires each railroad to describe the process that it will use to ensure that it is complying with the requirements of the training plans as required by this part.

NY MTA commented that the training required under this part should apply only to railroads that contract out their operations. NY MTA believed that contractors who are not responsible for actual railroad operations will be governed by the then-forthcoming Training Standards Rule, which proposed to require these contractors to certify that they have trained their employees on all the appropriate safety protocols

Requiring a SSP training component for certain railroad employees and officers is necessary because FRA's Training Standards Rule would not cover such SSP training for each type of employee or officer that this final rule describes as needing the training. As discussed *supra,* in late 2014, FRA published the final Training Standards Rule. 79 FR 66460. Generally, the Training Standards Rule requires each railroad or contractor that employs one or more "safety-related railroad employee" as defined by § 243.5, to develop and submit a training program to FRA for approval and to designate the minimum qualifications for each occupational category of employee. 49 CFR part 243. Some employees and officers required by paragraph (i) to receive system safety training would be considered a "safety-related railroad employee" under the Training Standards Rule and others would not. Since all employees and officers required to receive system safety program training under this final rule would not be required to receive such training pursuant to the Training Standards Rule, FRA declines to narrow the applicability of paragraph (i) as suggested by NY MTA. Furthermore, having a training component in this final rule does not create a duplicate training program filing requirement or require duplicate training as the Training Standards Rule specifically permits an employer to elect to cross-reference training programs or plans required by other FRA regulations in a part 243 submission, rather than resubmitting that program or plan for additional FRA review and approval. 49 CFR 243.103(b). As on-the-job training (OJT) is not expected to be a requirement of any SSP training program or plan, the provision of § 243.103(b) that mentions adding an OJT component would not be applicable to this final rule.

Paragraph (j), proposed as paragraph (k) in the NPRM, requires that a railroad's SSP plan describe the processes used by the railroad to manage emergencies that may arise within its system. A strong SSP will include effective emergency management processes. This description will allow FRA, during initial plan review and subsequent audits, to understand the railroad's emergency management processes, assess whether the railroad is complying with them, and determine if the processes adequately cover potential emergencies. FRA did not receive any comments in response to the proposal; its text remains unchanged in this final rule. The description must include the processes the railroad uses to comply with the applicable emergency equipment standards in part 238 of this chapter and the passenger train emergency preparedness requirements in part 239 of this chapter.

Paragraph (k), proposed as paragraph (l) in the NPRM, requires that the railroad's SSP plan describe the programs that the railroad has established that protect the safety of its employees and contractors. The description must include: (1) The processes that have been established to help ensure the safety of employees and contractors while working on or in close proximity to the railroad's property as described in paragraph (d) of this section; (2) the processes to help ensure that employees and contractors understand the requirements established by the railroad pursuant to paragraph (f)(1) of this section; (3) any fitness-for-duty programs or any medical monitoring programs; and (4) the standards for the control of alcohol and drug use in part 219 of this chapter.

Workplace safety is an integral part of a railroad's SSP and has a significant impact on railroad safety. Workplace safety touches many of the elements embedded in a SSP and should also be part of the railroad's overall safety philosophy and culture. This description will allow FRA, during initial plan review and subsequent audits, to understand the railroad's workplace safety programs and determine whether the railroad's SSP sufficiently addresses any gaps in the programs.

The NPRM originally proposed that the statement "describe any" of the programs and processes listed; however, FRA believes that this may have indicated that a railroad would not be required to describe all of the programs and processes listed, which was not the intent. FRA has revised the language to make clear that a railroad is required to describe all of the programs and processes listed. FRA also notes that proposed paragraph (k)(3) listed "fatigue management programs established by this part" as one of the fitness-for-duty programs to be described. However, as discussed in the Statutory Background section, to minimize confusion regarding the separate FMP Working Group process and the ongoing fatigue management plans rulemaking, the placeholder in this rule for fatigue management plans, paragraph (s), has been deleted. Therefore, the proposed requirement in paragraph (k)(3) that the railroad describe "fatigue management programs established by this part" has not been included in this final rule.

Moreover, in the NPRM, paragraph (k)(3) proposed that the statement include a description of "fitness-for-duty programs, including standards for the control of alcohol and drug use contained in part 219 of this chapter, and medical monitoring programs." However, the standards under part 219 are not necessarily "fitness-for-duty programs." Therefore, to minimize the potential for confusion, the final rule separates the required description of any fitness-for-duty programs or any medical monitoring programs (paragraph (k)(3)) from the description of the standards for the control of alcohol and drug use in part 219 of this chapter (included as paragraph (k)(4)). This change from the NPRM does not add to or remove any of the substantive requirements proposed in the NPRM.

Employees and contractors of the railroad are exposed to many hazards and risks while on railroad property. A railroad's SSP is required to take into consideration the safety of these persons and the programs and processes the railroad already has in place to address the hazards they face and resulting risks. As explained in the discussion of paragraph (g)(4), FRA is always concerned with the safety of employees in performing their duties; however, employee safety in maintenance and servicing areas generally falls within the jurisdiction of OSHA. It is not FRA's intent in this rule to displace OSHA's jurisdiction regarding the safety of employees while performing inspections, tests, and maintenance, except where FRA has already addressed workplace safety issues, such as blue signal protection. As with paragraph (g), FRA requested comment on whether it is necessary to include in the final rule a provision making clear that FRA does not intend to displace OSHA's jurisdiction over certain subject matters. Paragraph (g)(4) was included in response to the comments received and that provision makes clear that nothing in this rule, including paragraph (k), is intended to displace OSHA's jurisdiction.

The Labor Organizations raised a concern on whether paragraph (k) would create new, if any, rights for carriers to use fitness-for-duty programs and medical monitoring programs to undermine the forthcoming statutory-mandated fatigue management program. The Labor Organizations requested that FRA make clear in the final rule that the SSP regulation is not a fitness-for-duty or medical standards regulation. Neither paragraph (k) nor the SSP rule as a whole create any new rights regarding fitness-for-duty or medical monitoring programs, consistent with FRA's intent.

Paragraph (l), proposed as paragraph (m) in the NPRM, requires a railroad to establish and describe in its SSP plan the railroad's public safety outreach program to provide safety information to the railroad's passengers and the general public. Paragraph (l) also requires the railroad's safety outreach program to have a means in which railroad passengers and the general public can report hazards to the railroad.

A railroad's passengers and the general public play a vital role in the success of the railroad's SSP. The public safety outreach program requires the railroad to directly communicate safety information to both passengers and the general public and also allow these individuals to alert the railroad about safety hazards they observe. FRA will review the programs during the initial SSP plan review and subsequent audits to determine if the railroad's SSP sufficiently addresses any gaps in the programs.

FRA did not receive any comments in response to this paragraph; however, as proposed in the NPRM, paragraph (l) did not require a railroad's safety outreach to include a means for railroad passengers and the general republic to report hazards.

As proposed in the NPRM, a railroad's safety outreach program would only provide safety information to railroad passengers and the general public, which was not the intent. While it is important for a railroad's safety outreach program to provide the necessary safety information to the railroad's passengers and to the general public so that they can minimize their exposure to the hazards and resulting risks on the railroad and take appropriate precautions, it is not the sole purpose of the program. FRA believes that it is also important for railroad passengers and the general public to provide the railroad with information regarding any hazards they observed. This information will allow the railroad to address these identified hazards and resulting risks and improve the safety of the overall railroad and the safety information provided to the railroad passengers and the general public.

Paragraph (m), proposed as paragraph (n) in the NPRM, requires that a railroad's SSP plan describe the processes that the railroad uses to receive notification of accidents/incidents, investigate and report those accidents/incidents, and develop, implement, and track any corrective actions found necessary to address an investigation's finding(s). These processes should already be in place because they are necessary to comply with the requirements of part 225 of this chapter. Accidents and incidents can reveal hazards and risks on the railroad's system, which the railroad can then address as part of its SSP. While 49 CFR part 225 sets forth FRA's accident/incident reporting requirements, this section focuses on the actions the railroad will take to address accident/incident investigation results. These actions are important to the overall safety of a railroad's operations and will provide information to the railroad on what additional actions it can take as part of its SSP to address the hazards and resulting risks that contributed to the accident/incident.

FRA did not receive any comments in response to this paragraph as proposed in the NPRM. However, FRA has modified the paragraph to address "accidents/incidents"—rather than just "accidents," as proposed. This makes clear FRA's intent that the paragraph covers events that provide the railroad with information that may improve the safety of the railroad, which is not exclusive to accidents.

Paragraph (n), proposed as paragraph (o) in the NPRM, requires a railroad to establish and describe in its SSP plan processes that the railroad has or puts in place to collect, maintain, analyze, and distribute safety data in support of the SSP. Accurate safety data collection and the analysis and distribution of that data within a railroad can help the railroad determine where safety problems or hazards exist, develop targeted programs to address the problems and hazards, and focus resources towards the prevention of future incidents and improvement of safety culture. This description will assist FRA's review of these programs during the initial SSP plan review and audits to determine if the railroad's SSP sufficiently addresses any gaps in the programs. As proposed in the NPRM, paragraph (n) did not require a railroad to establish processes to collect, maintain, analyze, and distribute safety data in support of the SSP. Since some railroads will not have a SSP in place before the effective date of this final rule, FRA determined that it was necessary to include the requirement that a railroad not only describe but also establish SSP data acquisition processes. This ensures that a railroad has these processes in place and that it can be properly described pursuant to this paragraph. The data acquisition process described in APTA's System Safety Manual provides guidance on the processes a railroad may use to comply with this part.

Paragraph (o), proposed as paragraph (p) in the NPRM, requires a railroad's SSP plan to describe the process(es) it employs to address safety concerns and hazards during the safety-related contract procurement process. This applies to safety-related contracts to help ensure that the railroad can address as necessary safety concerns and hazards that may result from the procurement. FRA did not receive any comments in response to this proposed paragraph. However, the term "process" was changed to "process(es)" to recognize that a railroad may have more than one process in place.

The main components of a SSP are the risk-based hazard management program and the risk-based hazard analysis. The railroad will use the risk-based hazard management program to describe the various methods, processes, and procedures it will employ to properly and effectively identify, analyze, and mitigate or eliminate hazards and resulting risks. In turn, through the risk-based hazard analysis the railroad will actually identify, analyze, and determine the specific actions it will take to mitigate or eliminate the hazards and the resulting risks. Paragraphs (p) and (q), proposed as paragraphs (q) and (r) in the NPRM, set forth the elements of the railroad's risk-based hazard management program and risk-based hazard analysis. Both of these paragraphs implement sections 20156(c) through (f). FRA received multiple comments addressing the risk-based hazard management program and the risk-based hazard analysis, and these comments are addressed accordingly.

The risk-based hazard management program will be a fully implemented program within the railroad's SSP. Paragraph (p) requires a railroad to establish and describe the various methods, processes, and procedures that, when implemented, will identify, analyze, and mitigate or eliminate hazards and the resulting risks on the railroad's system. This paragraph embodies FRA's intent to provide each railroad with the flexibility to tailor its

SSP to its specific operations. Paragraph (p) does not set forth rigid requirements for a risk-based hazard management program. Rather, more general guidelines are provided and the railroad is able to apply these general guidelines to its specific operations.

APTA commented that paragraph (p) and paragraph (q), Risk-based hazard analysis, do not contain a discussion of the variety of controls or the flexibility this SSP rule provides to the railroads to choose which procedures they will put into place to mitigate or eliminate risks. APTA points out there was substantial discussion at the RSAC on this issue and it was recognized that there are many methods a railroad can apply to keep risk as low as reasonably practicable. APTA further points out that the analysis methods were grouped by RSAC into non-formal (*e.g.,* 5 Y method) and formal (*e.g.,* fault trees and cut sets). APTA therefore requests that FRA clarify that the understandings reached by the RSAC, and which were voted upon as recommendations, are still available as tools and have not been replaced by a formal analysis required by paragraphs (p) and (q).

FRA makes clear that the rule does not limit the methods a railroad may use in its risk-based hazard management program. FRA recognizes that there was agreement in the RSAC that many methods exist to keep risk low, such as MIL–STD–882 or the Government Electronics & Information Technology Association 010 Standard. However, this rule does not prescribe which of these methods must be used. Specifically, the discussion in the NPRM of proposed paragraph (q)(5) (paragraph (p)(1)(i) of the final rule) explained that the railroad would determine the methods it would use in the risk-based hazard analysis in proposed paragraph (r) (paragraph (q) of the final rule), to identify hazards on various aspects of its system. FRA intends that each railroad use this opportunity to use known methods and consider any new or novel techniques or methods to identify hazards that best suits that railroad's operations.

FRA notes that paragraph (p) is structured differently from what was proposed in the NPRM; however, the substance of paragraph (p) remains the same.

Paragraph (p)(1) requires the railroad's risk-based hazard management program to contain eight elements. All of these elements will be fully described in the railroad's SSP plan. First, the railroad shall establish the processes or procedures that will be used in the risk-based hazard analysis to identify the hazards on the railroad's system. This will be the railroad's opportunity to consider any new or novel techniques or methods that best suit the railroad's operations to identify hazards.

Second, the railroad must establish the processes or procedures that will be used in the risk-based hazard analysis that will analyze the identified hazards and, therefore, support the risk-based hazard management program. These processes and procedures will allow the railroad to analyze the hazards and, thus, gain the necessary knowledge to effectively identify the resulting risk.

Third, the railroad must establish the methods that will be used in the risk-based hazard analysis to determine the severity and frequency of hazards and to determine the corresponding risk. Once the railroad has identified the hazards, it will determine the corresponding risk. By developing a method that effectively identifies the severity and frequency of the hazards and determines the resulting risks, the railroad will be able to effectively prioritize the mitigation or elimination of the hazards and resulting risks.

In its comments on the NPRM, Parsons Brinckerhoff inquired as to FRA's intent behind using the terms "calculate" and "resulting risk" in the proposed rule text for paragraph (p)(1)(iii). Parsons Brinckerhoff questioned if FRA's use of the term "calculate" meant that the estimation of the resulting risk should be quantitative and that the use of the term "resulting risk" meant that the risk is a precise product of determining severity and consequence of hazards. Parsons Brinckerhoff suggested replacing "calculate the resulting risk" with "determine the corresponding risk" so that paragraph (p)(1)(iii) is more consistent with paragraph (p)(1)(iv) and allows for a broader range of risk assessment methodologies, which may include: Quantitative, semi-quantitative, qualitative, or some combination of all three. FRA agrees that the estimation of the risk does not necessarily have to involve a formal quantitative analysis, and therefore FRA adopts Parsons Brinckerhoff's suggested language.

Fourth, the railroad must establish the methods that will be used in the risk-based hazard analysis to identify the actions that mitigate or eliminate hazards and corresponding risks. Here the railroad will identify the methods or techniques it will use to determine which actions it will need to take to mitigate or eliminate the identified hazards and risks. As is the case with identifying the hazards and resulting risks, this is the railroad's opportunity to consider any new or novel methods best suited to the railroad's operations to mitigate or eliminate hazards and resulting risks. FRA recognizes that not all hazards and resulting risks can be eliminated or even mitigated, due to costs, feasibility, or other reasons. However, FRA expects the railroads to consider all reasonable actions that may mitigate or eliminate hazards and the resulting risks and to implement those actions that are best suited for that railroad's operations.

Fifth, the railroad must establish the process that will be used in the risk-based hazard analysis to set goals for the risk-based hazard management program and how performance against the goals will be reported. Establishing clear and concise goals will play an important role in the success of a railroad's risk-based hazard management program. The goals should be tailored so that the central goal of the risk-based hazard management program (to effectively identify, analyze, and mitigate or eliminate hazards and resulting risks) is supported for the individual railroad.

Sixth, the railroad must establish a process to make decisions that affect the safety of the rail system relative to the risk-based hazard management program. Railroads make numerous decisions every day that affect the safety of the rail system and this paragraph requires a railroad to describe how those decisions will be made when they relate to the risk-based hazard management program. FRA notes that Parsons Brinckerhoff commented whether this paragraph was meant to address risk acceptance, based on its reading of the discussion of this paragraph in the NPRM. Parsons Brinckerhoff requested that FRA revise this paragraph to make that clear, if it was FRA's intent.

Risk acceptance is a process in which an organization determines the appropriate level of risk to accept. An organization will determine which risks are acceptable based on the resources available to mitigate or eliminate those risks. While risk acceptance is an integral part of a SSP, FRA does not intend this paragraph to establish a risk acceptance requirement. Rather, the overall risk-based hazard management program, in part, establishes a risk acceptance framework for the railroad.

Seventh, the railroad must establish the methods that will be used in the risk-based hazard analysis to support continuous safety improvement throughout the life of the rail system. Consistent with the overall SSP, the railroad will implement methods as part of the risk-based hazard management program that will support continuous safety improvement.

Eighth, the railroad must establish the methods that will be used in the risk-based hazard analysis to maintain records of identified hazards and risks and the mitigation or elimination of the identified hazards and risks throughout the life of the rail system. In this paragraph the railroad will describe how it plans to maintain the records of the results of the risk-based hazard analysis. The railroad will also describe how it will maintain records of the mitigation or elimination of the identified hazards and risks. FRA notes that the proposal in the NPRM expressly addressed only the description of the methods used to maintain records of mitigating the identified hazards and risks. Because the hazards and risks maybe be eliminated by the railroad—not just mitigated—the text of this paragraph in the final rule makes clear that records of the elimination of the identified hazards and risks are covered as well. As a separate matter, while the railroad will not be required to provide in its SSP plan submission to FRA any of the specific records addressed by this paragraph, the railroad will be required to make the results of the risk-based hazard analysis available upon request to representatives of FRA pursuant to § 270.201(a)(2).

Paragraph (p)(2) requires the risk-based hazard management program to identify certain key individuals. First, the railroad must identify the position title of the individual(s) responsible for administering the risk-based hazard management program. These positions will be responsible for developing and implementing the risk-based hazard management program. Rather than identifying the specific individual(s), the railroad will identify the position(s) responsible for administering the risk-based hazard management program so that the SSP will not have to be updated merely because an individual changes positions. This clarification addresses an AAR comment on the NPRM in which AAR opposed the proposed requirements in paragraphs that the railroad identify the individuals responsible for administering the hazard management program and participating in hazard management teams or safety committees. AAR believes the problem with identifying such individuals is that whenever one of these individuals is removed or added, the plan must be amended and no real purpose is served. As a result, FRA makes clear that the final rule only requires the identification of the position titles, not the specific individuals.

Second, the railroad must identify the stakeholders who will participate in the hazard management program. This means the railroad will identify the persons who will be affected by and may play a role in the risk-based hazard management program.

Third, the railroad must identify the position title of the participants and structure of any hazard management teams or safety committees that a railroad may establish to support the risk-based hazard management program. By establishing these types of teams or committees, the railroad can focus on specific hazards and risks and more thoroughly consider the specific actions to effectively mitigate or eliminate the hazards and risks.

Paragraph (q), proposed as paragraph (r) in the NPRM, provides that once FRA has approved a railroad's SSP plan pursuant to § 270.201(b), the railroad shall conduct a risk-based hazard analysis. Paragraph (q)(1) serves to implement the section 20156(c) statutory mandate that a railroad must conduct a "risk analysis." As discussed earlier, section 20156(c) requires the railroad, as part of its development of a railroad safety risk reduction program (*e.g.,* a SSP), to "identify and analyze the aspects of its railroad, including operating rules and practices, infrastructure, equipment, employee levels and schedules, safety culture, management structure, employee training, and other matters, including those not covered by railroad safety regulations or other Federal regulations, that impact railroad safety." *Id.* Paragraph (q)(1) follows the language of section 20156(c); however, in the list of the aspects of the railroad system that must be analyzed, paragraph (q)(1) does not include "safety culture." Safety culture, which paragraph (b)(2) of this section requires the railroad to describe, is not something that a railroad can necessarily "identify and analyze" as readily as the other aspects listed. Nonetheless, the railroad must describe how it measures the success of its safety culture pursuant to paragraph (t) of this section.

As proposed in the NPRM, paragraph (q)(1) originally included employee fatigue as identified in proposed paragraph (s), in the list of the aspects of the railroad system that must be analyzed. However, as discussed in the Statutory Background section above, to minimize confusion regarding the separate FMP Working Group process and the ongoing fatigue management plans rulemaking, proposed paragraph (s) has not been included in the final rule; therefore the requirement that the railroad analyze employee fatigue as part of its risk analysis is not included in paragraph (q)(1) of the final rule. FRA also notes that proposed paragraph (q)(1) included "new technology as identified in paragraph (s) of this section"; however, since paragraph (r) of the final rule addresses a separate analysis regarding new technology, including new technology in paragraph (q)(1) would be duplicative.

As provided in the final rule, paragraph (q)(1) requires a railroad to analyze operating rules and practices, infrastructure, equipment, employee levels and schedules, management structure, employee training, and other aspects that have an impact on railroad safety not covered by railroad safety regulations or other Federal regulations. Pursuant to paragraphs (d), (e), and (g) through (i) of this section, a railroad is required to describe in its plan its operating rules and practices, infrastructure, equipment, employee levels and schedules, management structure, and employee training; therefore, the analysis and identification of hazards and resulting risks regarding these aspects pursuant to paragraph (q)(1) should be straightforward. The railroad will determine which aspects of the railroad system have an impact on railroad safety that are not covered by railroad safety regulations or other Federal regulations. When analyzing the various aspects, the railroad will apply the risk-based hazard analysis methodology previously identified in paragraphs (p)(1)(i) through (iii) of this section.

In commenting on the NPRM, Parsons Brinckerhoff stated that paragraph (q)(1) proposed to require that railroads apply the risk-based hazard analysis up through the application of mitigations but that it would not require the railroads to achieve an acceptable level of risk. While the rule does not specifically require a railroad to reduce risk to an acceptable level, paragraph (q)(2) requires a railroad, in part, to implement specific actions that will mitigate or eliminate the identified hazards and resulting risks. FRA believes that requiring railroads to achieve an acceptable level of risk would set forth an ambiguous standard because, due to differences in the size and complexity of passenger railroad operations, an acceptable level of risk for one railroad may not necessarily be the same for another railroad. Requiring a railroad to implement specific actions that will mitigate or eliminate the identified hazards and resulting risks will reduce risk and if FRA determines that a railroad is not properly addressing and reducing risk, FRA will work with the railroad and other stakeholders to address this issue and may take enforcement action if necessary.

Parsons Brinckerhoff also believed that proposed paragraph (q)(1) would not require the application of the risk-based hazard management program to support continuous safety improvement throughout the life of the rail system. Pursuant to paragraph (p)(1)(vii), the railroad will be required to describe the methods it will implement as part of the risk-based hazard management program that will support continuous safety improvement throughout the life of the rail system. Further, as discussed below, pursuant to paragraph (q)(3) a railroad will be required to conduct a risk-based hazard analysis when there are significant operational changes, system extensions, system modifications, or other circumstances that have a direct impact on railroad safety. FRA believes paragraphs (p)(1)(vii) and (q)(3) support continuous safety improvement throughout the life of the rail system.

Once the railroad has analyzed the various aspects of its operations and identified hazards and the resulting risks, the railroad is required to mitigate or eliminate these risks. This requirement is derived directly from section 20156(d), which requires a railroad, as part of its SSP, to have a risk mitigation plan that mitigates the aspects that increase risks to railroad safety and enhances the aspects that decrease the risks to railroad safety. In paragraph (q)(2), the railroad will use the methods described in paragraph (p)(1)(iv) to identify and implement specific actions to mitigate or eliminate the hazards and risks identified by paragraph (q)(1).

FRA makes clear that a risk-based hazard analysis is not a one-time event. Railroads operate in a dynamic environment and certain changes in that environment may expose new hazards and risks that a previous risk-based hazard analysis did not address. Paragraph (q)(3) identifies the changes that FRA believes are significant enough to require that a railroad conduct a new risk-based hazard analysis. Railroads must conduct a risk-based hazard analysis when there are significant operational changes, system extensions, system modifications, or other circumstances that have a direct impact on railroad safety.

As part of its SSP plan, paragraph (r), proposed as paragraph (s) in the NPRM, requires a railroad to conduct a technology analysis and set forth a technology analysis and implementation plan. Paragraph (r) implements sections 20156(d)(2) and 20156(e). Paragraph (r) has been substantially modified from the proposal in the NPRM. As proposed in the NPRM, this paragraph would have required railroads to first conduct a technology analysis, then establish a technology implementation plan containing the results of the technology analysis, and, if the railroad determined to implement any of the technologies, establish a plan and a prioritized implementation schedule for the development, adoption, implementation and maintenance of the technologies over a 10-year period.

FRA believes that the technology analysis and implementation plan requirements should be consistent with the risk-based hazard management program and risk-based hazard analysis requirements. Therefore, FRA has modified paragraph (r) from the proposed rule to ensure that it is consistent with these other requirements. A railroad, in its SSP plan submission to FRA, will describe the process it will use to: (1) Identify and analyze technologies that will mitigate or eliminate the hazards identified by the risk-based hazard analysis, and (2) analyze the safety impact, feasibility, and costs and benefits of implementing the identified technologies. The initial submission to FRA is required to describe only the processes the railroad will use to identify and analyze technology that will mitigate or eliminate hazards and the resulting risks.

The requirement that the railroad "periodically update as necessary" its technology analysis and implementation plan has been added to paragraph (r)(1). This was not proposed in the NPRM; however, section 20156(e) requires the plan to be periodically updated as necessary.

As with the overall SSP, the railroads will have flexibility to determine the processes they will use pursuant to paragraph (r)(2). One of the purposes of the technology analysis and implementation plan is to provide railroads and their stakeholders the opportunity to consider current, new, and novel technology to address hazards and the resulting risks; therefore, FRA encourages the railroads to consider as many different types of technology as possible.

Once FRA reviews and approves a railroad's technology analysis and implementation plan, as part of the SSP plan approval process, the railroad will apply the process identified in paragraph (r)(2)(i) to identify and analyze current, new, or novel technologies that will mitigate or eliminate the hazards and resulting risks identified by the risk-based hazard analysis. As with risk-based hazard analysis, the railroad will not conduct its technology analysis until after FRA has approved its technology analysis and implementation plan. Section 20156(e)(2) mandates that a railroad consider certain technologies as part of its technology analysis. These technologies are: Processor-based technologies, positive train control systems, electronically-controlled pneumatic brakes, rail integrity inspection systems, rail integrity warning systems, switch position monitors and indicators, trespasser prevention technology, and highway-rail grade crossing warning and protection technology.

Once the railroad has identified and analyzed current, new, or novel technologies that will mitigate or eliminate the hazards and resulting risks, the railroad shall apply the processes described in paragraph (r)(2)(ii) to analyze the safety impact, feasibility, and costs and benefits of implementing these technologies. FRA expects the railroads to engage in an appropriate and realistic analysis of the technologies. FRA is not requiring that a railroad use a specific formula to determine whether it should implement any of the technology analyzed in the technology analysis. Rather, the railroad must consider the safety impact, feasibility, and the costs and benefits of these technologies and, based on the railroad's specific operations, decide whether to implement any of the technologies. Technology has proved to be an invaluable tool to manage hazards across all modes of transportation, and a robust SSP certainly needs to include risk mitigation technology.

If a railroad decides to implement any of the technologies identified in paragraph (r)(3), the railroad would be required to update its technology analysis and implementation plan in its SSP to describe how it will develop, adopt, implement, maintain, and use the technologies. This description should be sufficient to allow FRA and other interested stakeholders to determine which technologies the railroad will implement, how they will be implemented, how the technologies will eliminate or reduce hazards and the resulting risks, and how the technologies will be maintained. The railroad will also be required to set forth in its SSP plan a prioritized implementation schedule for the development, adoption, implementation, and maintenance of those technologies over a 10-year period. By establishing this implementation schedule, the railroad will be able to describe its plan as to how it will apply technology on its system to mitigate or eliminate the identified hazards and resulting risks.

Paragraph (r)(5) provides that, except as required by 49 CFR part 236, subpart I (Positive Train Control Systems), if a railroad decides to implement a positive train control (PTC) system as part of its technology implementation plan, the railroad shall set forth and comply with a schedule for implementation of the PTC system consistent with the deadlines in the Positive Train Control Enforcement and Implementation Act of 2015 (PTCEI Act), Public Law 114–73, 129 Stat. 576–82 (Oct. 29, 2015), and 49 CFR 236.1005(b)(7). The NPRM proposed that the railroad would have to implement the PTC system by December 31, 2018, which was consistent with 49 U.S.C. 20156(e)(4)(B). However, Congress subsequently passed the PTCEI Act and FRA has revised paragraph (r)(5) to reflect the changes to PTC implementation deadlines set forth in the Act. This paragraph does not, in itself, require a railroad to implement a PTC system. In the NPRM, FRA sought comment on whether a railroad electing to implement a PTC system would find it difficult to meet the December 31, 2018 implementation deadline. If so, FRA invited comment as to what measures could be taken to assist a railroad struggling to meet the deadline and achieve the safety purposes of the statute. FRA received one comment in response to this request. AAR commented that it does not object to this requirement but that it is impossible to meet the 2015 deadline for an interoperable nationwide PTC system that complies with the statutory-mandate. Consequently, AAR believes that no railroad will take advantage of paragraph (r)(5). FRA recognizes the challenges associated with implementing a PTC system; however, FRA also recognizes that PTC is a technology that a railroad may seek to implement to eliminate or mitigate hazards and the resulting risks. Therefore, the regulation provides railroads the flexibility to decide whether they want to implement a PTC system as part of their technology analysis and implementation plan; if they do so, they must comply with an implementation schedule consistent with the deadlines in the PTCEI Act.

Consistent with the risk-based hazard analysis, a railroad will not include its technology analysis conducted pursuant to paragraph (r)(3) in the SSP submission to FRA under § 270.201. The SSP plan should only include the processes used to conduct its technology analysis as described in paragraph (r)(3). FRA may work with the railroads to ensure that the technology analysis is robust and analyzes a sufficient number of technologies. To achieve this goal, FRA, its representatives, and States participating under part 212 of this chapter will have access to the railroad's technology analysis pursuant to paragraph (r)(5). Furthermore, in its initial submission, a railroad will not include the description and implementation schedule required by paragraph (r)(4) because the railroad will not draft the description and implementation schedule until FRA approves the railroad's technology analysis and implementation plan.

Paragraph (s) sets forth the requirements for ensuring that safety issues are addressed whenever there are certain changes to the railroad's operations. Paragraph (s)(1) requires each railroad to establish and set forth a statement in its SSP plan that describes the processes and procedures used by the railroad to manage significant operational changes, system extensions, system modifications, or other circumstances that will have a direct impact on railroad safety. Since these changes have a direct impact on safety, it is vital that the railroad has a process to manage these changes so that safety is not compromised. Change management processes ensure that, when there is a need for a change to a safety-critical program, the proposed change is vetted through a formalized process within the organization. This description will assist FRA's review of these processes during the initial SSP plan review and subsequent audits to determine if the railroad's SSP sufficiently addresses any gaps in the processes. The term "significant changes that will have a direct impact on railroad safety" is intended to be broadly understood; however, the other changes listed (significant operational changes, system extensions, system modifications) are the type of changes that will also necessitate a process/procedure to properly manage them.

Paragraph (s)(2) requires each railroad to establish in its SSP plan a configuration management program. The term configuration management is defined in § 270.5 as a process that ensures that the configurations of all property, equipment, and system design elements are accurately documented. Accordingly, the railroad's configuration management program shall: (1) Identify who within the railroad has authority to make configuration changes; (2) establish processes to make configuration changes to the railroad's system; and (3) establish processes to ensure that all departments of the railroad affected by the configuration change are formally notified and approve of the change. Configuration management is a process that ensures that all safety-critical documentation relating to the railroad and its various components is current and reflects the actual functional and physical characteristics of the railroad. This description will assist FRA's review of these processes during the initial SSP plan review and subsequent audits to determine if the railroad's SSP sufficiently addresses any gaps in the processes.

Paragraph (s)(3) requires the railroad to establish and describe in its SSP plan the process it uses to certify that safety concerns and hazards are adequately addressed before the initiation of operations or major projects to extend, rehabilitate, or modify an existing system or repair vehicles and equipment. Through a process certifying that safety concerns have been addressed before the railroad initiates operations or major projects to extend, rehabilitate, or modify an existing system or replace vehicles and equipment, the railroad helps to minimize the potential for any negative impact on safety resulting from any of these activities.

In commenting on the NPRM, APTA states that safety certifications are not common in commuter rail operations mostly because these railroads follow FRA regulations and standards and most, if not all, safety certifications have been performed because an FTA funding agreement required one to be performed. According to APTA, FTA does not have a set of regulations and standards to allow operation on the general railroad system of transportation that applies to all railroads under FTA's jurisdiction. Without these national standards, APTA notes that FTA and transit properties rely on design criteria and best engineering practices, and since these design criteria differ at each transit agency, safety certification is the method relied upon to ensure the system is safe. APTA believes that it would be a rare occasion when a commuter railroad would be required to perform a safety certification under paragraph (s)(3) and that the paragraph uses the term "major projects" without elaboration. APTA does not believe that every project will need safety certification unless it falls outside of FRA's existing standards. APTA therefore recommends that FRA clarify the term "major projects" by adding to the end of the sentence: "not otherwise addressed by existing FRA standards."

FRA expects every major project to be designed and built so that it meets or exceeds existing FRA standards. However, paragraph (s)(3) requires a process that certifies the major project is in compliance with these FRA standards or with appropriate design criteria, or both. Safety certification is part of APTA's Manual for the Development of System Safety Program Plans for Commuter Railroads. Section 6 of APTA's manual, Safety Assurance, contains Element 22, Configuration Management, and within Element 22 is section 6.1.1.4, Safety Certification. Section 6.1.1.4 states: ''Safety Certification is used to oversee the addition and introduction of completely new systems and the integration to the existing system if the project is not a new start. The US DOT Federal Transit Administration and APTA have jointly published a manual on how to conduct a safety certification program.'' A railroad is free to use the standards published in the manual/guide that APTA and FTA have developed regarding safety certification to comply with paragraph (s)(3).

As discussed previously, a SSP can only be effective at mitigating or eliminating hazards and risks if the railroad has a robust and positive safety culture. Pursuant to § 270.101(b), the railroad will design its SSP so that it promotes and supports a positive safety culture; pursuant to § 270.103(b)(2), the railroad will identify in its SSP plan its safety culture; and pursuant to paragraph (t) a railroad will describe in its SSP plan how it measures the success of its safety culture. A railroad cannot have a robust safety culture unless it actively promotes it and evaluates whether it is successful. With respect to measuring safety culture, the rule permits railroads to identify the safety culture measurement methods that they find most effective and appropriate for their own operations. It is important that a railroad regularly measure its safety culture. This measurement may be based upon the DOT's 10 traits of a positive safety culture discussed above or the Nuclear Regulatory Commission's nine traits. *See* 76 FR 34777–78, Jun. 14, 2011. The key is to be continuously measuring because organizational culture, which safety culture is a part of, can change. Measuring to determine a positive safety culture demonstrates that there is a clear connection, and inverse relationship, between safety culture and event occurrence. Measuring safety culture, such as findings from previous employee assessments, demonstrates that there is a positive relationship between safety culture and employee engagement which supports improved decision-making. When measuring safety culture, FRA expects a railroad to use a method that is capable of correlating a railroad's safety culture with actual safety outcomes. A safety culture assessment focuses on the people side of safety—cultural behaviors that enable, equip, and empower—such as communication, trust, leadership, commitment, peer group norms and organizational influences. For example, such measurement methods can include surveys that assess safety culture using validated scales, or some other method or measurement that appropriately identifies aspects of the railroad's safety culture that correlate to safety outcomes. Ultimately, FRA expects a railroad to demonstrate that improvements in the measured aspects of safety culture will reliably lead to reductions in accidents, injuries, and fatalities.

Measuring safety culture that is done on a regular basis would be very difficult to establish costs and benefits. As discussed above DOT has 10 traits to guide the measurement of safety culture. A number of different tools have been developed to measure safety culture, and are used in various industries, including aviation and certain manufacturing sectors. To illustrate, one research review listed 24 different tools used to measure safety culture in the health care industry alone.[6] It is important to note that each tool measures factors using its own scale, and the scales are not calibrated across the different tools. Calibration is the process of finding a mathematical relationship between different scales—the Fahrenheit and Celsius temperature scales are calibrated, for example, so it is possible to convert a reading from one scale to the other. Thus, although in the aggregate many studies suggest there is a link between improved safety culture and decreases in accidents or injuries,[7] it is not possible to definitively quantify the benefits that accrue due to improvements in safety culture. FRA recognizes that there are many ways to accomplish the task of measuring a railroad's safety culture. For purposes of this rule FRA will assume that this is accomplished with some type of survey instrument.[8]

Section 270.105 Discovery and Admission as Evidence of Certain Information

As discussed in the Statutory Background section, FRA's Study concluded that it is in the public interest to protect certain information generated by railroads from discovery or admission into evidence in litigation. Section 20119(b) provides FRA with the authority to promulgate a regulation if FRA determines that it is in the public interest, including public safety and the legal rights of persons injured in railroad accidents, to prescribe a rule that addresses the results of the Study.

Following the issuance of the Study, the RSAC met and reached consensus on recommendations for this rulemaking, including a recommendation on the discovery and admissibility issue. RSAC recommended that FRA issue a rule that would protect documents generated solely for the purpose of planning, implementing, or evaluating a SSP from (1) discovery, or admissibility into evidence, or considered for other purposes in a Federal or State court proceeding for damages involving property damage, personal injury, or wrongful death; and (2) State discovery rules and sunshine laws that could be used to require the disclosure of such information.

Section 270.105, Discovery and admission as evidence of certain information, sets forth the discovery and admissibility protections that are based on the Study's results and the RSAC recommendations. These protections are narrow and apply only to information that was generated solely for a railroad's SSP, and aim to ensure that a litigant will not be better or worse off than if the protections had never existed. FRA intends these provisions to be strictly construed.

FRA modeled § 270.105 after 23 U.S.C. 409. In section 409, Congress enacted statutory protections for certain information compiled or collected pursuant to Federal highway safety or construction programs. *See* 23 U.S.C. 409. Section 409 protects both data compilations and raw data. Intermodal Surface Transportation Efficiency Act of 1991, sec. 1035(a), 105 Stat. 1978; National Highway System Designation Act of 1995, sec. 323, 109 Stat. 591. A litigant may rely on section 409 to withhold certain documents from a discovery request, in seeking a protective order, or as the basis to object to a line of questioning during a trial or deposition. Section 409 extends this protection to information that has never been in any Federal entity's possession.

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[6] Health Foundation. ''Evidence scan: Measuring safety culture,'' *http://patientsafety.health.org.uk/sites/default/files/resources/measuring_safety_culture.pdf* as of October 30, 2014 (February, 2011) p. 7.

[7] O'Toole, Michael. ''The Relationship between employees' perceptions of safety and organizational culture,'' *The Journal of Safety Research,* 33 (2002) pp 231–243.

[8] One organization that provides safety culture surveys includes a price list on their Web site. Perhaps averaging a few such organizations' prices would help refine this estimate. See *http://www.nsc.org/safety_work/employee_perception_surveys/Pages/SurveyCosts.aspx* (showing costs for safety culture surveys of different levels of complexity).

Section 409 was enacted by Congress in response to concerns raised by the States that compliance with the Federal road hazard reporting requirements could reveal certain information that would increase the State's risk of liability. Without confidentiality protections, States feared that their "efforts to identify roads eligible for aid under the Program would increase the risk of liability for accidents that took place at hazardous locations before improvements could be made." *Pierce County* v. *Guillen,* 537 U.S. 129, 133–34 (2003) (citing H.R. Doc. No. 94–366, p. 36 (1976)).

The constitutionality and validity of section 409 has been affirmed by the Supreme Court of the United States. *See Pierce County* v. *Guillen.* In *Guillen,* the Court considered the application of section 409 to documents created pursuant to the Hazard Elimination Program, which is a Federal highway program that provides funding to State and local governments to improve the most dangerous sections of their roads. *Id.* at 133. To be eligible for the program, the State or local government must (1) maintain a systematic engineering survey of all roads, with descriptions of all obstacles, hazards, and other dangerous conditions; and (2) create a prioritized plan for improving those conditions. *Id.*

The Court held that section 409 protects information actually compiled or collected by any government entity for the purpose of participating in a Federal highway program, but does not protect information that was originally compiled or collected for purposes unrelated to the Federal highway program, even if the information was at some point used for the Federal highway program. *Guillen* at 144. The Court took into consideration Congress' desire to make clear that the Hazard Elimination Program "was not intended to be an effort-free tool in litigation against state and local governments." *Id.* at 146. However, the Court also noted that the text of section 409 "evinces no intent to make plaintiffs worse off than they would have been had section 152 [Hazard Management Program] funding never existed." *Id.* The Court also held that section 409 was a valid exercise of Congress' powers under the Commerce Clause because section 409 "can be viewed as legislation aimed at improving safety in the channels of commerce and increasing protection for the instrumentalities of interstate commerce." *Id.*

FRA believes that given the similar concepts between section 409 and section 20119 and the Supreme Court's expressed acknowledgement of the constitutionality of section 409, section 409 is an appropriate model for § 270.105.

Under § 270.105(a) there are certain circumstances in which information will not be subject to discovery, admitted into evidence, or considered for other purposes in a Federal or State court proceeding for damages involving personal injury, wrongful death, or property damage. This information may not be used in such litigation when it is compiled or collected solely for the purpose of planning, implementing, or evaluating a SSP. Section 270.105(a) applies to information whether or not it is also in the Federal government's possession.

FRA notes that paragraph (a) has been reformatted for clarity from the proposal in the NPRM. Paragraph (a) is divided into paragraph (a)(1) and (2) after its introductory text. However, the formatting change does not, in itself, result in any substantive change to the paragraph.

Paragraph (a)(1) describes what may be considered "information" for the purposes of this section. Section 20119(a) identifies reports, surveys, schedules, lists, and data as the forms of information that should be included as part of FRA's Study. However, FRA does not necessarily view this as an exclusive list. In the statute, Congress directed FRA to consider the need for protecting information that includes a railroad's analysis of its safety risks and its statement of the mitigation measures with which it will address those risks. *Id.* While the railroad is not required to provide in the SSP plan that it submits to FRA the results of the risk-based hazard analysis and the specific elimination or mitigation measures it will be implementing, the railroad may have a specific plan within its SSP that does contain this information. Therefore, to adequately protect this type of information, the term "plan" is included in the definition of "information" to cover a railroad's submitted SSP plan and any elimination or mitigation plans the railroad otherwise develops within its SSP. FRA also deems it necessary to include "documents" in this provision to maintain consistency and properly effectuate Congress' directive in section 20119.

This paragraph does not protect all information that is part of a SSP; these protections will extend only to information that is compiled or collected after August 14, 2017, solely for purpose of planning, implementing, or evaluating a system safety program. The term "compiled or collected" is taken directly from section 20119(a). FRA recognizes that railroads may be reluctant to compile or collect extensive and detailed information regarding the safety hazards and resulting risks on their systems if this information could potentially be used against them in litigation. The term "compiled" refers to information that was generated by the railroad for the purposes of a SSP; whereas the term "collected" refers to information that was not necessarily generated for the purposes of the SSP, but was assembled in a collection for use by the SSP. It is important to note that in this context, only the collection is protected; however, each separate piece of information that was not originally compiled for use by the SSP remains subject to discovery and admission into evidence subject to any other applicable provision of law or regulation.

Section 20119(b) prohibits the protections from becoming effective until one year after the adoption of the SSP rule. The necessary text has been added to paragraph (a) to implement this effective date.

The information has to be compiled or collected solely for the purpose of planning, implementing, or evaluating a SSP. APTA commented that the use of the term "solely" is not adequately explained in the text of the regulation. APTA proposes that FRA either use a more appropriate term such as "primarily" or "initially" or that FRA define "solely" in the rule text, not just in the preamble. FRA agrees. The use of the term "solely" is deliberate and it is important that the term is understood as used within the four corners of the regulation. Therefore, FRA has included paragraph (a)(2), which defines the term "solely."

As discussed in the section-by-section analysis for § 270.1(c), NY MTA recommended that the term "solely" be deleted from paragraph (a) to protect studies or risk analyses that are not developed expressly to comply with this part. NY MTA believes that it is in the public interest to ensure that railroads conduct on-going and thorough self-critical examinations and expressed concern if these types of studies or analyses are not protected, they may be used against the railroad in court. As discussed below in response to APTA's request that FRA extend the protections to information collected as part of programs that existed before the SSP regulation but were similar to a SSP, FRA has the authority to protect only documents that are created pursuant to a SSP; therefore, omitting the term "solely" would improperly expand the protections beyond the limits of FRA's authority.

The term "solely" is intended to narrow circumstances in which the information will be protected. The use of the term "solely" means that the original purpose of compiling or collecting the information was exclusively for the railroad's SSP. A railroad cannot compile or collect information for one purpose and then try to use paragraph (a) to protect that information because it uses that information for its SSP as well. The railroad's original and singular purpose of compiling or collecting the information must be for planning, implementing, or evaluating its SSP in order for the protections to be extended to that information. The term "solely" also means that a railroad shall continue to use the information only for its SSP. If a railroad subsequently uses, for any other purpose, information that was initially compiled or collected for its SSP, paragraph (a) does not protect that information to the extent that it is used for the non-system safety program purpose. The use of that information within the railroad's SSP, however, will remain protected. If the railroad is required by another provision of law or regulation to collect the information, the protections of paragraph (a) do not extend to that information because it is not being compiled or collected solely for the purpose of planning, implementing, or evaluating a SSP. For example, 49 CFR 234.313 requires railroads to retain records regarding emergency notification system (ENS) reports of unsafe conditions at highway-rail grade crossings. Those individual records are not protected by § 270.105. However, if as part of its risk-based hazard analysis a railroad collects several of its § 234.313 reports from a specific time period for the sole purpose of determining if there are any hazards at highway-rail grade crossings, this collection will be protected as used in the SSP. If the railroad decides to use the collection for another purpose other than in its SSP, such as submitting it to an ENS maintenance contractor for routine maintenance, the protections are not extended to that non-SSP use.

The information must be compiled or collected solely for the purpose of planning, implementing, or evaluating a SSP. The three terms—planning, implementing, or evaluating—are taken directly from section 20119(a). These terms cover the necessary uses of the information compiled or collected solely for the SSP. To properly plan and develop a SSP, a railroad will need to determine the proper processes and procedures to identify hazards, the resulting risks, and elimination or mitigation measures to address those hazards and risks. This planning will involve gathering information about the various analysis tools and processes best suited for that particular railroad's operations. This type of information is essential to the risk-based hazard analysis and is information that a railroad does not necessarily already have. In order for the railroad to plan its SSP, the protections are extended to the SSP planning stage. The NPRM used the term "developing" instead of "planning"; however, to remain consistent with section 20119(a), FRA has determined that the term "planning" is more appropriate.

Based on the information generated by the risk-based hazard analysis, the railroad will implement measures to eliminate or mitigate the hazards and risks identified. To properly implement these measures, the railroad will need the information regarding the hazards and risks on the railroad's system identified during the development stage. Therefore, the protection of this information is extended to the implementation stage.

The protections do not apply to information regarding mitigations that the railroad implements. Rather, the railroad's statement of mitigation measures, which could include various proposed and alternate mitigations for a specific hazard, that address the hazards identified by the risk-based hazard analysis is protected. Additionally, the underlying risk analysis information that the implemented mitigation measure addresses is also protected. For instance, if a railroad builds a structure to address a risk identified by the risk-based hazard analysis, the information regarding that structure (*e.g.*, blueprints, contracts, permits, etc.) is not protected by this section; however, the underlying risk-based hazard analysis that identified the hazard and any statement of mitigations that included the structure is protected.

The protections also do not apply to any hazards, risks, or mitigations that fall under the exclusive jurisdiction of another Federal agency. If FRA does not have jurisdiction over a hazard, risk, or mitigation, then the protections under this paragraph cannot be extended to that hazard, risk, or mitigation.

The railroad will also be required to evaluate whether the measures it implements to mitigate or eliminate the hazards and risks identified by the risk-based hazard analysis are effective. To do so, it will need to review the information developed by the risk-based hazard analysis and the methods used to implement the elimination/mitigation measures. The use of this information in the evaluation of the railroad's SSP is protected.

The information covered by this section shall not be subject to discovery, admitted into evidence, or considered for other purposes in a Federal or State court proceeding that involves a claim for damages involving personal injury, wrongful death, or property damage. The protections affect the discovery, admission into evidence, or consideration for other purposes of the information described in this section. The first two situations come directly from section 20119(a); however, FRA determined that for the protections to be effective they must also apply to any other situation where a litigant might try to use the information in a Federal or State court proceeding that involves a claim for damages involving personal injury, wrongful death, or property damage. For example, under this section a litigant will be prohibited from admitting into evidence a railroad's risk-based hazard analysis. Nonetheless, without the additional language: "or considered for other purposes," the railroad's risk-based hazard analysis could be used by a party for the purpose of refreshing the recollection of a witness or by an expert witness to support an opinion. The additional language ensures that the protected information remains out of such a proceeding completely. The protections would be ineffective if a litigant were able to use the information in the proceeding for another purpose. To encourage railroads to perform the necessary vigorous risk analysis and to implement truly effective elimination or mitigation measures, the protections are extended to any use in a proceeding.

This section applies to Federal or State court proceedings that involve a claim for damages involving personal injury, wrongful death, or property damage. This means, for example, if a proceeding has a claim for personal injury and a claim for property damage, the protections are extended to that entire proceeding; therefore, a litigant cannot use any of the information protected by this section as it applies to either the personal injury or property damage claim. Section 20119(a) required the Study to consider proceedings that involve a claim for damages involving personal injury or wrongful death; however, to effectuate Congress' intent behind section 20156, that railroads engage in a robust and candid hazard analysis and develop meaningful mitigation measures, FRA has determined that it is necessary for the protections to be extended to proceedings that involve a claim solely for property damage. The typical railroad accident resulting in injury or death also involves some form of property damage. Without extending the protection to proceedings that involve a claim for property damage, a litigant could bring two separate claims arising from the same incident in two separate proceedings, the first for property damages and the second one for personal injury or wrongful death, and be able to conduct discovery regarding the railroad's risk analysis and to introduce this analysis in the property damage proceeding but not in the personal injury or wrongful death proceeding. This would mean that a railroad's risk analysis could be used against the railroad in a proceeding for damages. If this were the case, a railroad would be hesitant to engage in a robust and candid hazard analysis and develop meaningful elimination or mitigation measures. Such an approach would be nonsensical and would completely frustrate Congress' intent in providing FRA the ability to protect that information which is necessary to ensure that open and complete risk assessments are performed and appropriate mitigation measures are selected and implemented. Therefore, to be consistent with Congressional intent behind section 20156, FRA has decided to extend the protections in paragraph (a) to proceedings that involve a claim for property damage. Furthermore, RSAC, which includes railroads and rail labor organizations as members, recommended to FRA that the protections be extended in this way to proceedings that involve a claim for property damage.

Paragraph (b) ensures that the protections set forth in paragraph (a) do not extend to information compiled or collected for a purpose other than that specifically identified in paragraph (a). This type of information shall continue to be discoverable, admissible into evidence, or considered for other purposes if it was before the date the protections take effect. The type of information that will not receive the protections provided by paragraph (a) include: (1) Information that was compiled or collected on or before August 14, 2017; (2) information that was compiled or collected on or before August 14, 2017, and continues to be compiled or collected, even if used to plan, implement, or evaluate a railroad's SSP; or (3) information that is compiled or collected after August 14, 2017, for a purpose other than that specifically identified in paragraph (a) of this section. Paragraph (b) affirms the intent behind the use of the term "solely" in paragraph (a), in that a railroad may not compile or collect information for a different purpose and then expect to use paragraph (a) to protect that information just because the information is also used in its SSP. If the information was originally compiled or collected for a purpose unrelated to the railroad's SSP, then it is unprotected and will continue to be unprotected.

Examples of the types of information that paragraph (b) applies to may be records related to prior incidents/accidents and reports prepared in the normal course of railroad business (such as inspection reports). Generally, this type of information is often discoverable, may be admissible in Federal and State proceedings, and should remain discoverable and admissible where it is relevant and not unduly prejudicial to a party after the implementation of this part. However, FRA recognizes that evidentiary decisions are based on the facts of each particular case; therefore, FRA does not intend this to be a definitive and authoritative list. Rather, FRA merely provides these as examples of the types of information that paragraph (a) is not intended to protect.

In commenting on the NPRM, the Labor Organizations requested that FRA provide a list of examples of information that is currently discoverable and admissible and will remain so after the enactment of the protections. The Labor Organizations pointed out that such a list was provided to FRA during the Risk Reduction Working Group deliberations and they would like the list to be placed in the discussion of the final rule. While the list that was provided was instructive, as mentioned in the previous paragraph, evidentiary decisions are based on the facts of each particular case and a court's ruling in one case does not guarantee that another court's ruling in another jurisdiction will be the same. FRA believes that the examples provided in the previous paragraph are more than sufficient to provide a general idea of the types of information covered by paragraph (b) that are not protected.

APTA requested that FRA extend the protections to information collected as part of programs that existed before the SSP regulation but were similar to a SSP. APTA pointed out that this information will now be collected under the SSP rule and therefore should receive the protections provided by paragraph (a). APTA believes that the exclusions in paragraph (b) will incentivize railroads with existing SSP-like programs to shut down their programs in anticipation of this part because the information from the SSP-like programs will not be protected even if it were collected as part of the SSP under this part. While FRA understands APTA's concern, FRA does not have the authority to provide retroactive protection to information that was compiled or collected before the protections take effect. The study section 20119(a) mandated only addresses information compiled and collected pursuant to the statutory-mandated risk reduction program. Since a SSP is a risk reduction program mandated by statute (section 20156), the information protections can only be extended to information compiled or collected pursuant to a SSP. This means that any information compiled or collected before the protections take effect is not protected because that is not information compiled or collected pursuant to a SSP. Furthermore, since this is information compiled or collected before the protections take effect, the fact that after the protections take effect the information will be compiled or collected pursuant to the SSP does not mean that the information will then be protected. By virtue of the information being compiled or collected before the SSP rule protections take effect, it is not information collected "solely" for the SSP that is protected by this rule. To clarify this distinction, FRA has included language in the exception in paragraph (b)(2).

Pursuant to paragraph (b)(2), if a railroad compiled or collected certain information that was subject to discovery, admissibility, or consideration for other purposes before the protections take effect and the railroad continues to collect the same type of information pursuant to its SSP required by this part, that information will not be protected by paragraph (a) of this section. For example, before this section takes effect and all else being equal, a litigant that would have been able to have admitted into evidence certain information the railroad compiled will still be able to have that type of information admitted after this section takes effect even if the railroad compiles the information pursuant to this rule. The protections are designed to apply only when the original purpose for the generation of the information was for a SSP required by this part. The original purpose of the generation of the information for the SSP-like programs that existed before the SSP rule would not be for a SSP required by this part; therefore, such information is not protected by paragraph (a).

Paragraph (b)(3) reaffirms that information that is compiled or collected for a purpose other than solely for the purpose of planning, implementing, or evaluating a SSP, shall not be protected.

This section is not intended to replace any other protections provided by law or regulation. Accordingly, paragraph (c) states that the protections set forth in this section will not affect or abridge in any way any other protection of information provided by another provision of law or regulation. Any such provision of law or regulation shall apply independently of the protections provided by this section.

Paragraph (d) clarifies that a litigant cannot rely on State discovery rules, evidentiary rules, or sunshine laws that could be used to require the disclosure of information that is protected by paragraph (a) in a Federal or State court proceeding for damages involving personal injury, wrongful death, or property damage. This provision is necessary to ensure the effectiveness of the Federal protections established in paragraph (a) in situations where there is a conflict with State discovery rules or sunshine laws in a Federal or State court proceeding for damages involving personal injury, wrongful death, or property damage. The concept that Federal law takes precedence where there is a direct conflict between State and Federal law should not be controversial as it derives from the constitutional principal that "the Laws of the United States . . . shall be the supreme Law of the Land." U.S. Const., Art. VI. Additionally, FRA notes that 49 U.S.C. 20106 is applicable to this section. Section 20106 provides that States may not adopt or continue in effect any law, regulation, or order related to railroad safety or security that covers the subject matter of a regulation prescribed or order issued by the Secretary of Transportation (with respect to railroad safety matters) or the Secretary of Homeland Security (with respect to railroad security matters), except when the State law, regulation, or order qualifies under the "essentially local safety or security hazard" exception to section 20106. In this regard, FRA's Study concluded that a rule "limiting the use of information collected as part of a railroad safety risk reduction program in discovery or litigation" furthers the public interest by "ensuring safety through effective railroad safety risk reduction program plans" (*see* Study at 64); FRA concurs in this conclusion.

NY MTA commented that it is in the public interest to protect risk analysis information from production in response to FOIA requests and State freedom of information laws. NY MTA requested that the protection from these types of information disclosure laws be applied to information about system vulnerabilities that could be of interest to terrorist threats. As discussed in the Statutory Background section, section 20118(c) gives FRA the discretion to prohibit the public disclosure of risk analyses or risk mitigation analyses obtained under other FRA regulations if FRA determines that the prohibition of public disclosure is necessary to promote public safety. Furthermore, if a railroad believes that certain risk analysis information qualifies as Sensitive Security Information (SSI), the information can be submitted to FRA for such a determination. If FRA determines the information qualifies as SSI or if the railroad has some other acceptable basis for requesting confidential treatment, pursuant to 49 CFR 209.11, the information will be appropriately marked and handled, which includes redacting it from any publicly disclosed documents.

Section 20119(b) mandates that the effective date of any rule prescribed pursuant to that section must be one year after the adoption of that rule. As discussed in the Statutory Background section, FRA is developing, with the assistance of the RSAC, a separate risk reduction rule that would implement the requirements of sections 20156, 20118, and 20119 for Class I freight railroads and railroads with inadequate safety performance. In the NPRM for this final rule, FRA proposed to apply the protections and the exceptions for SSP information proposed in that NPRM to the information in the forthcoming RRP final rule. The effect of that proposal would have been to make the protections for the forthcoming RRP final rule applicable one year after the publication of this final rule establishing part 270 rather than one year after publication of the RRP final rule. FRA sought comment on this proposal and received one comment from APTA, who supported the proposal.

After further consideration, FRA has determined to implement the RRP protections in the RRP final rule rather than in this rule. Because section 20119(b) states that "*[a]ny* such rule prescribed pursuant to this subsection shall not become effective until 1 year after its adoption," FRA has concluded that the RSIA requires that each rule's implementing information protections must have its own independent implementation timeline. (Emphasis added.) FRA believes this revised approach is a better reflection of the Congressional intent in section 20119(b). Further, the revised approach ensures that FRA has complied with notice and comment procedures of the Administrative Procedure Act for both the SSP and RRP rulemakings.

Section 270.107 Consultation Requirements

This section implements section 20156(g)(1), which states that a railroad required to establish a SSP must "consult with, employ good faith and use its best efforts to reach agreement with, all of its directly affected employees, including any non-profit employee labor organization representing a class or craft of directly affected employees of the railroad carrier, on the contents of the safety risk reduction program." This section also implements section 20156(g)(2), which further provides that if a "railroad carrier and its directly affected employees, including any nonprofit employee labor organization representing a class or craft of directly affected employees of the railroad carrier, cannot reach consensus on the proposed contents of the plan, then directly affected employees and such organizations may file a statement with the Secretary explaining their views on the plan on which consensus was not reached." Section 20156(g)(2) requires FRA to consider these views during review and approval of a railroad's SSP plan. The consultation requirements were proposed in § 270.102 of the NPRM; however, to remain consistent with CFR section numbering format, this section is designated as § 270.107 in this final rule.

RSAC did not provide recommended language for this section. Rather, FRA worked with the System Safety Task Group to receive input regarding how the consultation process should be addressed, with the understanding that language would be provided in the NPRM for review and comment. In response to consultation process language proposed in the NPRM, FRA received comments from AAR, APTA, Labor Organizations, Metra, NY MTA, and an individual commenter.

The Labor Organizations commented that FRA improperly classified the process under section 20156(g) as one of consultation. The Labor Organizations believe that section 20156(g) requires a process of negotiation or bargaining with the directly affected employees, not one of consultation. Nothing in the text of section 20156(g) requires railroads to negotiate or bargain with directly affected employees; rather, the statute requires the railroads to "consult with, employ good faith and use [their] best efforts to reach agreement with'' directly affected employees (including the Labor Organizations) on the contents of the SSP plan. Throughout the RSAC discussions, FRA referred to this process as one of consultation, not one of negotiation or bargaining. The proposed text in the NPRM is consistent with section 20156(g), and FRA does not agree with the Labor Organizations' belief that the statute requires a process of negotiation or bargaining. Requiring a process of negotiation and bargaining would be beyond the scope of section 20156(g).

APTA believes that the consultation requirements in the final rule should mirror text in section 20156(g), and nothing more is needed. Specifically, APTA believes that anything more than the statutory text would be counter-productive, interfere with business relationships, and blur the line between FRA and the National Labor Relations Board's (NLRB) responsibilities. FRA disagrees. FRA believes that § 270.107 and the accompanying Appendix clarify and provide a workable framework for the railroads. As for the blurring of FRA's and NLRB's responsibilities, APTA did not provide any examples in which FRA proposed to intrude upon NLRB's responsibilities. It isn't clear, therefore, to which NLRB responsibilities APTA is referring.

Paragraph (a)(1) of this section implements section 20156(g)(1) by requiring a railroad to consult with its directly affected employees on the contents of its SSP plan. As part of that consultation, a railroad must utilize good faith and best efforts to reach agreement with its directly affected employees on the contents of its plan. APTA requested that FRA expand the consultation requirement to include all parties, including the directly affected employees and those with significant safety responsibilities because, as proposed, the rule would not require any entities other than the railroads to consult in good faith. APTA is concerned that some railroads may not have authority or leverage to successfully bring the other parties to the table during the consultations. FRA agrees that all of the necessary entities should participate in the consultation process; however, section 20156(g) requires only the railroad to employ good faith and use its best efforts to reach agreement with all of its directly affected employees. Pursuant to paragraph (b)(2), if the railroad and certain directly affected employees cannot reach agreement, the railroad will provide a consultation statement to FRA that identifies any known areas of non-agreement and an explanation of why the railroad believes agreement was not reached. This will be the railroad's opportunity to explain whether the result of non-agreement is due to the directly affected employees not acting in good faith or not using their best efforts. Pursuant to paragraph (c), the employees will then have the opportunity to file a statement which will be their opportunity to explain why they or why the railroad believes they did not use good faith or best efforts. Since section 20156(g) requires only the railroad to act in good faith and use best efforts, FRA may approve a plan even if the directly affected employees did not act in good faith or did not use their best efforts, just as long as the railroad employed good faith and best efforts. This means that a railroad will satisfy section 20156(g) if it can show that it acted in good faith and used best efforts to reach agreement, even if other parties did not. FRA believes this will provide the ''authority'' or ''leverage'' raised by APTA for a railroad to bring the necessary parties to the table. The directly affected employees will not be able to block approval of a railroad's SSP plan by not acting in good faith or using their own best efforts, as APTA suggests. Rather, the consultation process is the opportunity for the directly affected employees to provide input and work with the railroad to create a SSP plan that addresses any issues the employees believe are critical to the safety of the railroad. If the directly affected employees fail to act in good faith or do not use their best efforts, they will miss an opportunity to have their voices fully heard and may end up being required to comply under the regulation with a SSP plan in which they did not effectively provide input.

APTA also requested that the consultation process be modified so that the process provides a structure for working collaboratively in the development of the SSP and a methodology to handle disputes or reasonable differences in opinion on how to implement the plan. FRA believes that § 270.107 and Appendix B provide a workable, but flexible framework so that the parties can work collaboratively on the development of a SSP and handle any disputes that arise. APTA did not provide any suggestions regarding what type of modifications should be made, so it is unclear to FRA what in the rule should be modified from the NPRM.

Paragraph (a)(2) as proposed in the NPRM specified that the term directly affected employees included any non-profit employee labor organization representing a class or craft of the railroad's directly affected employees. The proposed paragraph made it clear that a railroad that consults with a non-profit employee labor organization is considered to have consulted with the directly affected employees represented by that organization. However, FRA has removed this language from paragraph (a)(2) and incorporated it into paragraphs (a)(1) and (2).

Paragraph (a)(2) clarifies that if a railroad contracts out significant portions of its operations, the contractor and the contractor's employees performing the railroad's operations shall be considered directly affected employees for the purposes of this part. While this provision was not expressly proposed in the NPRM, FRA believes it is necessary to address how the consultation process will be handled when a railroad contracts out significant portions of its operations to other entities. The contracts should be ongoing and involve significant aspects of the railroad's operations. For example, if a railroad contracts out maintenance of its locomotives and rail cars to another entity, it is vital for the employees who are performing this maintenance to be part of that railroad's SSP and have the opportunity to provide their valuable input on the SSP. Another example would be if a railroad contracts out the actual operations of its passenger rail to another entity; the contracted entity that is operating the trains on behalf of the railroad would certainly need to be part of the consultation process. If a railroad is unsure whether a contracted entity is a directly affected employee for the purposes of this part, FRA encourages the railroads and other interested stakeholders to contact FRA for guidance.

Paragraph (a)(3) in the NPRM proposed to require a railroad to meet with its directly affected employees no later than 180 days after the effective date of the final rule to discuss the consultation process. This requirement has been included in paragraph (a)(3) of the final rule. This meeting will be the railroad's and directly affected employees' opportunity to schedule, plan, and discuss the consultation process. FRA does not expect a railroad to discuss any substantive material until the information protections provisions of § 270.105 become applicable. Because some commenters appeared to believe that this meeting would discuss the substance of the SSP plan, FRA is including language in paragraph (a)(3) specifying that the railroad is not required to discuss the substance of a SSP plan. Rather, this meeting should be administrative in nature so that all parties understand the consultation process as they go forward and that they may engage in substantive discussions as soon as possible after the protections of § 270.105 become applicable. The meeting will also be an opportunity for the railroad to educate the directly affected employees on system safety and how it may affect them. Under paragraph (a)(3)(ii), the railroad will be required to provide notice to the directly affected employees no less than 60 days before the meeting is held.

In commenting on the NPRM, the Labor Organizations pointed out that the meeting under paragraph (a)(3) is the only meeting required by this rule and there is no requirement to have a meeting to discuss the substance of the SSP plan. The Labor Organizations believe that meetings regarding the substance of the SSP plan can occur before the protections of § 270.105 become applicable, because in the past with other programs (*e.g.,* the Confidential Close Call Reporting Program), the railroads and the Labor Organizations have agreed to confidentiality. As stated in the previous paragraph, the meeting required by paragraph (a)(3) will be the railroad's and the Labor Organizations' opportunity to schedule and plan the consultation process. This means that at the first meeting, the parties will schedule the future meetings to discuss the substance of the SSP plan. Since every railroad operation varies by scale and work force, FRA believes setting forth a rigid consultation meeting schedule would be unworkable and inconsistent with the flexibility that the SSP aims to provide. The initial meeting under paragraph (a)(3) provides both the railroad and the labor organizations the flexibility to tailor the consultation process to their specific needs. Additionally, FRA has extended the time between the date that the § 270.105 information protections are applicable and when the railroads will be required to submit their SSP plans, thereby extending the amount of time during which consultation on the substance of the SSP plans will occur. As for consultation on the substance of a SSP plan before the date the § 270.105 protections are applicable, nothing in the rule restricts any railroad from doing so, and if the parties can enter into a confidentiality agreement regarding this information, they are free to do so. FRA does note, however, that any such confidentiality agreement is unrelated to this rule and would not affect the use of any such information in legal proceedings, to the extent otherwise permitted by law.

The Labor Organizations also expressed concern with the amount of time estimated in the rule's Paperwork Reduction Act analysis for the railroads to consult with the directly affected employees and the amount of time to prepare a statement under paragraph (b)(2). The Paperwork Reduction Act analysis estimated that each railroad would have four consultation meetings at 4 hours each for a total of 16 hours and that a statement under paragraph (b)(2) would take 20 minutes to prepare. The Labor Organizations claim that these estimated time periods are too short and would result in an inconsequential amount of time for consultation on the contents of the plan. FRA notes that the time periods in the Paperwork Reduction Act analysis were only estimates and comments were requested on these estimates. *See* 77 FR 55401. The Labor Organizations' comments do not provide suggested time periods that they believe are more appropriate. However, in this final rule, FRA has reevaluated the burdens under the Paperwork Reduction Act and is providing new estimates based on the Labor Organizations' concerns. FRA has increased its estimate of the number of consultations with directly affected employees to 28 and has increased the burden time of each consultation to 40 hours. Further, FRA has increased the number of consultation statements to 30. Of these, 28 consultation statements will take 80 hours to complete and two consultations will take two hours to complete

Multiple commenters requested FRA modify the timeline in paragraph (a)(3). APTA believes that the proposed consultation (and SSP implementation) schedule is not practical and may not be possible to comply with. APTA states that the requirement to have the initial consultation with the directly affected employees within 180 days of the effective date of the rule is not reasonably achievable. According to APTA, some railroads would be hard pressed to meet this deadline due to the size of their operations and the variety of directly affected employees they would be required to notify. APTA proposes that, rather than requiring the initial consultation to be completed, § 270.201 should require that the initial consultation only begin within the 180 days. FRA notes that § 270.107(a)(3) requires the railroad only to meet "to discuss the consultation process," not to complete the initial consultation process. As discussed in the previous paragraph, this meeting will be administrative in nature and FRA does not expect the railroad to discuss the substance of the SSP plan. FRA makes clear that it does not expect the railroad to complete an initial consultation on the substance of the SSP plan within this 180-day period; rather, it is understandable that the railroad will wait until the date the § 270.105 protections become applicable before it begins the consultation on the substance of the plan. APTA also requested that the deadline to file the SSP plan pursuant to § 270.201 be extended so that there would be more time to consult with the directly affected employees on the substance of the SSP plan. FRA is extending this time period as discussed in the section-by-section analysis for § 270.201(a), below.

NY MTA and Metra proposed that FRA extend the 180-day deadline for the meeting to 365 days due to the number of employees working under numerous contracts that would need to meet to discuss the consultation process. FRA declines to extend this 180-day period to 365 days because it would be inconsistent with the purpose of requiring the meeting. As discussed above, this meeting will be administrative in nature and FRA does not expect the meeting to address the substance of the SSP plan. If the time period were extended to 365 days after the effective date of the rule, a railroad could hold the initial meeting on day 364, and 121 days[9] later the railroad would be required to submit the SSP plan to FRA. This would make it very difficult for the railroads and directly affected employees to initiate and complete the consultation process in a timely and meaningful manner. Instead, by having the initial meeting within 180 days after the effective date of the rule, all parties will have a clear understanding of the consultation process, so that once the meetings begin regarding the substance of the SSP plan (presumably after the date the § 270.105 protections become applicable), the parties can focus on the SSP plan and not the actual consultation process.

NY MTA also commented that the consultation process should not even begin until after the date the protections in § 270.105 become applicable because protection is needed to ensure that railroads and employees are not discouraged from actively identifying hazards. FRA agrees that the consultation regarding the substance of a SSP plan could not fully begin until after the date the § 270.105 protections become applicable, which is why the meeting required by paragraph (a)(3) is required only to address the consultation process, not the substance of the SSP plan.

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[9] Based on comments received, the deadline to submit SSP plans to FRA pursuant to § 270.201 is extended to 545 days after the publication of the final SSP rule. This is discussed further in the section-by-section analysis for § 270.201(a)(1). The statement that a railroad would have 121 days to submit an SSP plan takes into account this extension of the submission deadline.

Finally, Metra requested that FRA clarify that the 60-day notification requirement only applies to the initial meeting to discuss the consultation process, and no other meeting. FRA agrees and has included paragraph (a)(3)(ii), which is based on the last sentence of proposed paragraph (a)(3). Paragraph (a)(3)(ii) provides that a railroad shall notify the directly affected employees of the preliminary meeting no less than 60 days before it is held, thereby clarifying that the 60-day period refers only to this preliminary meeting.

Paragraph (a)(4) directs readers to Appendix B for additional guidance on how a railroad might comply with the consultation requirements of § 270.107. The appendix and the comments received in response are discussed later in this preamble in the section-by-section analysis for the Appendix B.

An individual commenter requested that the consultation requirements be more detailed. The commenter suggested adding the following requirements: (1) Visibly post the SSP requirements under this part before the SSP is created because, according to the commenter, the parties tend to get "dug in" once the consultation begins and everyone has expressed their position; (2) hold biannual or quarterly meetings between parties regarding safety hazards and risks and provide the meeting minutes to FRA; (3) have a system in which perceived unsafe work orders can be challenged; (4) do not allow a fully implemented SSP to be changed in a way that reduces safety without FRA approval; and (5) establish a committee to make recommendations on uniform minimum standards for working on the right-of-way, including intercity rail.

As for the commenter's first and second suggested requirements, FRA seeks to provide the railroads and their directly affected employees the flexibility to tailor the consultation process to their specific operations. Therefore, adopting these requirements would only take away some of this flexibility. The commenter's third suggested requirement is actually a type of mitigation measure a railroad may put in place to address identified hazards and resulting risks. However, FRA is not requiring specific mitigation measures under this rule; consequently, FRA declines to adopt the suggested mitigation measure. The commenter's fourth suggested requirement raises an issue that is addressed in § 270.201(c), below. Finally, regarding the commenter's fifth suggested requirement, FRA's RSAC has established working groups and task forces to addresses safety across a wide range of areas, including right-of-way safety. In fact, the safety of roadway workers along the right-of-way is specifically addressed in FRA's regulations at 49 CFR part 214. Accordingly, FRA believes it unnecessary to adopt this suggested requirement.

Paragraph (b) requires a railroad to submit, together with its SSP plan, a consultation statement. The purpose of this consultation statement is twofold: (1) To help FRA determine whether the railroad has complied with § 270.107(a) by, in good faith, consulting with and using its best efforts to reach agreement with its directly affected employees on the contents of its SSP plan; and (2) to ensure that the directly affected employees with which the railroad has consulted are aware of the railroad's submission of its SSP plan to FRA for review. The consultation statement must contain specific information described in paragraphs (b)(1) through (4) of this section.

Paragraph (b)(1) requires that the consultation statement contain a detailed description of the process the railroad utilized to consult with its directly affected employees. This description should contain information such as (but not limited to) the following: (1) How many meetings the railroad held with its directly affected employees; (2) what materials the railroad provided its directly affected employees regarding the draft SSP plan; and (3) how input from directly affected employees was received and handled during the consultation process.

If the railroad is unable to reach agreement with its directly affected employees on the contents of its SSP plan, paragraph (b)(2) requires that the consultation statement identify any known areas of disagreement and provide the railroad's explanation for why it believed agreement was not reached. A railroad could specify, in this portion of the statement, whether it was able to reach agreement on the contents of its SSP plan with certain directly affected employees, but not others.

In commenting on the NPRM, AAR believes that paragraph (b)(2) should be removed. AAR states that a railroad cannot know the motivation behind its directly affected employees' decision (including a labor union's decision) to disagree with a railroad's SSP plan. FRA agrees that the railroad may not know the actual reason(s) why its directly affected employees could not reach agreement with it on the contents of the SSP plan. It is because of this that paragraph (b)(2) requires an explanation only as to why the railroad believes agreement was not reached—not what the directly affected employees believe. If agreement cannot be reached, this statement will provide a record of the railroad's account of the consultation process, and in turn will serve to help FRA evaluate whether good faith and best efforts were used.

In the NPRM, § 270.102(b)(3) proposed to require that the consultation statement identify any provision that would affect a provision of a collective bargaining agreement between the railroad and a non-profit employee labor organization and then explain how the railroad's SSP plan would affect it. In commenting on the NPRM, AAR believes this proposal is unnecessary and requested that FRA delete it. FRA agrees and has not included this provision in the final rule. Generally, FRA is not involved in the collective bargaining process and does not intend to become involved in the process because of this rule. However, if the labor organizations believe that the railroad's SSP plan violates the collective bargaining agreement, they may include this as part of their statement pursuant to paragraph (c)(1) of this section.

Under paragraph (b)(3) in the final rule, proposed as paragraph (b)(4), the consultation statement must include a service list containing the name and contact information for the international/national president of any non-profit employee labor organization representing directly affected employees and any directly affected employee who significantly participated in the consultation process independently of a non-profit labor organization. This paragraph also requires a railroad (at the same time it submits its proposed SSP plan and consultation statement to FRA) to provide individuals identified in the service list a copy of the SSP plan and consultation statement. This service list will help FRA determine whether the railroad has complied with the § 270.107(a) requirement to consult with its directly affected employees. Requiring the railroad to provide individuals identified in the service list with a copy of its submitted plan and consultation statement also serves to notify those individuals that they have 30 days under § 270.107(c)(2) (discussed below) to submit a statement to FRA if they were not able to come to reach agreement with the railroad on the contents of the SSP plan.

As proposed in the NPRM, this paragraph would have required the consultation statement to include a service list containing the names and contact information for the international/national president and general chairperson of the non-profit employee labor organizations representing a class or craft of the railroad's directly affected employees; any labor organization representative who participated in the consultation process; and any directly affected employee who significantly participated in the consultation process independently of a non-profit employee labor organization. In its comments on the NPRM, AAR requested that the service list be limited to the international/national president of any non-profit employee labor organization representing a class or craft of the railroad's directly affected employees. AAR believes that including the general chairperson of these labor organizations and any labor organization representative who participated in the consultation process would be overly burdensome and that a railroad's inadvertent failure to serve one of the parties listed could be used against them and lead to FRA not approving the plan. AAR cites certain regulations of the Surface Transportation Board (STB) for which, when notification of labor unions is required, notice is given to the national office of the labor unions of the employee affected. *See* 49 CFR 1150.32(e) and 1150.42(e). AAR believes that service on the union presidents is sufficient because the unions are capable of notifying the necessary employees. FRA agrees. To minimize the paperwork burden and the potential for confusion, the service list under paragraph (b)(3) contains only the following: (1) The international/national president of any non-profit employee labor organization representing directly affected employees and (2) any directly affected employee who significantly participated in the consultation process independently of a non-profit employee labor organization. When directly affected employees are represented by a non-profit employee labor organization, limiting service to the president of the labor organization serves to ensure that the employees receive the same version of the SSP plan, thereby minimizing potential confusion.

In commenting on the NPRM, the Labor Organizations requested that when a railroad submits its SSP plan and consultation statement to FRA, the railroad also "simultaneously" send a copy of these documents to all individuals identified in the service list. FRA agrees and has adopted this suggestion to ensure the directly affected employees receive the SSP plan and consultation statement at approximately the same time FRA does so that they have sufficient time to submit a statement to FRA pursuant to paragraph (c)(2).

Finally, FRA notes that APTA, in commenting on the NPRM, believes that paragraph (b) applies different standards to the parties (railroads and directly affected employees) and presumes that failure to reach agreement would be based on the railroad's failure to use good faith. APTA recognizes that RSIA allows directly affected employees to file a statement with FRA regarding the areas of disagreement; however, APTA believes that paragraph (b) effectively shifts the burden to the railroads. APTA also claims that paragraph (b) presumes that if no agreement is reached, the SSP plan is deficient and the railroad failed to act in good faith, instead of considering the possibility that the SSP plan is adequate but the parties simply disagree. APTA therefore requests that proposed paragraphs (b)(1) through (3) not be included in the final rule.

As discussed previously, FRA has not included proposed paragraph (b)(3) in this final rule. FRA also makes clear that, if there is disagreement between the railroad and certain directly affected employees, including their union representatives, the failure to reach an agreement does not, in itself, lead to a presumption that the railroad acted in bad faith or failed to use best efforts. Rather, the consultation statement required by paragraph (b) is the railroad's opportunity to explain why it believes there was disagreement. If paragraphs (b)(1) and (2) were not included in the final rule, as requested by APTA, FRA would only have the statement from the directly affected employees as an explanation as to why agreement was not reached. To make a balanced and well-informed decision on whether the railroad used good faith and best efforts, FRA believes it necessary to have a statement from both the railroad and the directly affected employees. Further, as noted in the discussion of paragraph (a)(1), FRA may approve a plan even if there is disagreement between the parties, as long as FRA can determine that the railroad consulted in good faith and used its best efforts to reach agreement. In this regard, it would be more difficult for FRA to make this determination without the consultation statement required by paragraphs (b)(1) and (2).

Paragraph (c)(1) implements section 20156(g)(2) by providing that, if a railroad and its directly affected employees cannot reach agreement on the proposed contents of a SSP plan, then the directly affected employees may file a statement with the FRA Associate Administrator for Railroad Safety and Chief Safety Officer explaining his or her views on the plan on which agreement was not reached. The FRA Associate Administrator for Railroad Safety and Chief Safety Officer will consider any such views during the plan review and approval process. Appendix C sets forth the procedures for the submission of statements by directly affected employees.

Paragraph (c)(2) specifies that a railroad's directly affected employees have 30 days following the date of the railroad's submission of its proposed SSP plan to submit the statement described in paragraph (c)(1) of this section. While the NPRM proposed to provide the directly affected employees 60 days to file such a statement, FRA believes that 30 days is more appropriate. This decision takes into account that paragraph (b)(3) ensures that the directly affected employees are provided the SSP plan and the consultation statement at approximately the same time the documents are provided to FRA for review, as requested by the Labor Organizations. Moreover, pursuant to § 270.201(b), FRA will review a SSP plan within 90 days of receipt, as discussed below. As a result, if the directly affected employees were to have up to 60 days to submit a statement when agreement on the SSP plan was not reached, FRA would have only 30 days to consider the directly affected employees' views while reviewing the SSP plan. Thirty days would not be enough time to ensure that the directly affected employees' views are sufficiently addressed during the SSP plan review process.

Paragraph (d) requires that a railroad's SSP plan include a description of the process a railroad will use to consult with its directly affected employees on any substantive amendments to the railroad's SSP plan. As with its initial SSP plan, a railroad must use good faith and best efforts to reach agreement with directly affected employees on any substantive amendments to the plan. Examples of substantive amendments could include the following: The addition of new stakeholder groups (or the removal of a stakeholder group); major changes to the processes employed, including changes to the frequency of governing body meetings; or changing the organizational level of the manager responsible for the SSP (*e.g.,* changing from the Chief Safety Officer to someone who reports to the Chief Safety Officer). Requiring a railroad to detail that process in its plan facilitates the consultation by establishing a known path to be followed. A railroad that does not follow this process when substantively amending its SSP plan may be subject to penalties for failing to comply with the provisions of its plan. However, this requirement does not apply to non-substantive amendments (*e.g.,* amendments updating names and addresses of railroad personnel). If a railroad is uncertain as to whether a proposed amendment is substantive or non-substantive, it should contact FRA for guidance.

Subpart C—Review, Approval, and Retention of System Safety Program Plans

Section 20156(a)(1)(B) requires a railroad to submit its SSP, including any of the required plans, to the Administrator (as delegate of the Secretary) for review and approval. Subpart C, Review, Approval, and Retention of System Safety Program Plans, addresses these statutory requirements.

Section 270.201 Filing and Approval

This section sets forth the requirements for the filing of a SSP plan and FRA's approval process.

Paragraph (a)(1) requires that each railroad submit one copy of its SSP plan to the FRA Associate Administrator for Railroad Safety and Chief Safety Officer no later than February 8, 2018, or not less than 90 days before commencing operations, whichever is later. In the NPRM, FRA proposed requiring submission no later 395 days after the effective date of the final rule; however, many commenters expressed concern regarding this timeframe. The commenters believe that 395 days after the effective date of the rule is not a sufficient amount of time for a railroad to draft its SSP and conduct the necessary consultation with directly affected employees pursuant to § 270.107. The commenters point out that since the protections under § 270.105 do not go into effect until 365 days after the publication date of the rule, the requirement that the railroad submit its plan to FRA 395 days after the effective date does not provide enough time to conduct consultation regarding the substance of the SSP. To address these concerns, FRA has extended this submission deadline.

The final rule requires a railroad to submit its SSP plan 180 days after the effective date of the protections. Per section 20119(b), the protections cannot go onto effect until 1 year after adoption of the final rule. The final rule will not be effective until 60 days after publication. Therefore, 365 days after publication, the railroad will have 180 days to submit its SSP. In other words, the railroad will submit its SSP plan to FRA 545 days after publication or 485 days after the effective date of the rule. FRA believes providing the railroads with additional time to submit their plans will allow for sufficient time to draft the SSP plan and conduct the necessary consultation with the directly affected employees pursuant to § 270.107.

In addition, APTA raised concerns regarding the requirement that new starts submit their plans not less than 90 days before commencing operations. APTA believes this is not sufficient time if operations begin before the protections under § 270.105 are effective and therefore requests FRA consider extending the amount of time a railroad has to submit a plan before commencing operations. Under paragraph (a)(1), a railroad must have its SSP plan in place 90 days before commencing operations, or by February 8, 2018 (*i.e.,* 180 days after the date the protections of § 270.105 become applicable), whichever is later. This means that if a new start is commencing operations before the date the protections of § 270.105 become applicable, the railroad will have at least until 180 days after the date the protections of § 270.105 become applicable to submit a plan, given that the later submission date will apply. Accordingly, FRA believes that the rule provides a sufficient amount of time for a new start to develop its SSP plan in consultation with its directly affected employees and submit the plan to FRA for approval.

Paragraph (a)(2) provides that the railroad shall not include the results of its risk-based hazard analysis in its SSP plan that it submits to FRA pursuant to paragraph (a)(1) of this section. The SSP plan should only include the processes and methods used in the risk-based hazard analysis as described in § 270.103(p). However, since the risk-based hazard analysis is a vital element of a SSP, FRA will be available to assist the railroads and other stakeholders to ensure that this analysis is robust and addresses all the necessary aspects of the railroad's operations. To achieve this goal, representatives of FRA and States participating under part 212 of this chapter will have access to the railroad's risk-based hazard analysis pursuant to paragraph (a)(2).

As part of its submission, the railroad must provide certain additional information. Primarily, under paragraph (a)(3), the SSP plan submission shall include the signature, name, title, address, and telephone number of the chief official responsible for safety and who bears primary managerial authority for implementing the SSP for the submitting railroad. By signing, this chief official is certifying that the contents of the SSP plan are accurate and that the railroad will implement the contents of the program as approved by FRA. The SSP plan shall also include the contact information for the primary person managing the SSP and the senior representatives of host railroads, contract operators, and shared track/corridor operators, if any, and any other person who utilizes or provides significant safety-related services. The term "person" has been included in paragraph (a)(3)(iii) to clarify what was meant by "others" as proposed in the NPRM. The inclusion of a person that utilizes or provides significant safety-related services is consistent with the discussion of § 270.103(d)(2). The contact information for the primary person managing the SSP is necessary so that FRA knows who to contact regarding any issues with the railroad's SSP. Likewise, the contact information for the senior representatives of any host railroad, contract operator, shared track/corridor operator, or other person who utilizes or provides significant safety-related services is necessary so that FRA knows who to contact regarding the involvement of these parties in implementing and supporting the railroad's SSP. Separately, FRA notes that it has included proposed paragraph (a)(5) in paragraph (a)(3) to maintain clarity. Paragraph (a)(5) in the NPRM proposed to require the chief official responsible for safety and who bears primary managerial authority for implementing the railroad's SSP to certify that the contents of the railroad's SSP plan are accurate and that the railroad will implement the contents of the program as approved by § 270.201(b). This proposed requirement is specifically reflected in paragraph (a)(3)(i).

Paragraph (a)(4) references the requirements of § 270.107(b), which requires a railroad to submit with its SSP plan a consultation statement describing how it consulted with its directly affected employees on the contents of its SSP. When the railroad provides the consultation statement to FRA, § 270.107(b)(3) also requires that the railroad simultaneously provide a copy of the statement to certain directly affected employees identified in a service list. The directly affected employees can then file a statement for FRA's consideration in evaluating the proposed plan if they do so within 30 days after the railroad has filed its consultation statement, as discussed in § 270.107(c)(2).

Paragraph (b) sets forth the FRA approval process for a railroad's SSP plan. Within 90 days of receipt, FRA will review the SSP plan to determine if the elements prescribed in this part are sufficiently addressed in the railroad's submission. FRA notes that the NPRM also proposed that FRA review would alternatively take place "within 90 days of receipt of each SSP plan submitted before the commencement of railroad operations." However, FRA has not included this alternative condition in the final rule because it would be duplicative and erroneously imply a difference in the 90-day period, when there would be none. FRA's review will consider any statement submitted by directly affected employees pursuant to § 270.107. As with drafting the plan, FRA intends to work with the railroad and any necessary stakeholders when reviewing the plan.

Once FRA determines whether a railroad's SSP plan complies with the requirements of this part, FRA will notify, in writing, each person identified by the railroad in § 270.201(a)(3) whether the railroad's SSP plan is approved or not. The NPRM proposed that FRA notify "the primary contact person of each affected railroad"; however, to maintain consistency within this section, FRA revised the language to "each person identified by the railroad in § 270.201(a)(3)." If FRA does not approve a plan, it will inform the railroad of the specific points in which the plan is deficient. FRA will also provide the notification to each individual identified in the service list accompanying the consultation statement required under § 270.107(b). When the railroad receives notification that the plan is not approved and notice of the specific points in which the plan is deficient, the railroad has 90 days to correct all of the deficiencies identified and resubmit the plan to FRA under paragraph (b)(3). FRA had received comments expressing concern that 60 days was not a sufficient amount of time for a railroad to address the deficient points of a SSP plan, as proposed in the NPRM. To address this concern, FRA has extended the deadline to 90 days in the final rule.

AAJ and the Labor Organizations expressed concern that railroads may claim that they are immune from any safety hazard claim or that a State law claim is preempted because FRA has approved a railroad's SSP plan. The Labor Organizations provided the example that if an employee is injured because of defective ballast in a yard, and a State has a regulation that sets forth walkway standards, a railroad may claim that the State law is preempted because FRA had approved the railroad's SSP which included walkway safety. Accordingly, the Labor Organizations suggested the following language to address this concern: "Neither the approval by FRA of a railroad's System Safety Plan nor its compliance by a railroad shall be admitted into evidence in a lawsuit seeking damages for alleged negligence, nor shall a railroad claim that a state law or regulation is preempted, or that a federal law or regulation is precluded, because of such FRA approval or a railroad's compliance." FRA understands the concerns expressed by the commenters, and has included paragraph (b)(4) to address those concerns.

The final rule requires the development of a SSP that must be approved by FRA. Under § 270.103(p), the SSP includes a risk-based hazard management program that establishes the processes used in the risk-based hazard analysis to identify hazards and corresponding risks on the railroad's system and the methods used to identify actions that mitigate or eliminate the hazards and corresponding risks. Section 270.201(a)(2) provides that the railroad shall not include in its SSP the risk-based hazard analysis that is conducted pursuant to § 270.103(q). Section 270.103(q) in turn provides that once FRA approves a railroad's SSP, the railroad is to apply the risk-based hazard analysis to identify and analyze hazards on the railroad's system, determine the resulting risks, and identify and implement specific actions that will mitigate or eliminate the hazards. Since FRA will not be reviewing or approving the specific mitigation and elimination measures that a railroad may adopt to address the hazards and risks that it identifies, the final rule is not intended to preempt State standards of care regarding the specific risk mitigation and mitigation actions a railroad will implement under its SSP. Accordingly, § 270.201(b)(4) clarifies that FRA approval of a railroad's SSP plan under this final rule does not constitute approval of the specific mitigation and elimination measures that the railroad will implement pursuant to § 270.103(q)(2) and should not be construed as establishing a Federal standard of care regarding those specific actions.

Paragraph (c) addresses the process a railroad will follow whenever it amends its SSP. When a railroad amends its SSP plan it shall submit the amended SSP plan to FRA not less than 60 days before the proposed effective date of the amendment(s). The railroad shall file the amended SSP plan with a cover letter outlining the proposed changes to the original, approved SSP plan. The cover letter should provide enough information so that FRA knows what is being added, removed, or changed from the original approved SSP. The railroad will also be required to follow the process described pursuant to § 270.107(d) regarding the consultation with directly affected employees concerning the amendment(s) to the SSP plan. The railroad will describe in the cover letter the process it used to consult with its directly affected employees on the amendment(s).

FRA recognizes that some amendments may be safety-critical and that the railroad may not be able to submit the amended SSP plan to FRA 60 days before the proposed effective date of the amendments. In these instances, the railroad shall submit the amended SSP plan to FRA as near as possible to 60 days before the proposed effective date of the amendment(s). The railroad shall provide an explanation why the amendment is safety-critical and describe the effects of the amendment. The requirement that the railroad explain why the amendment is safety-critical was not proposed in the NPRM; however, it was added to the final rule to ensure that it is clear to FRA and other stakeholders the nature of the amendment and why the railroad believes it is safety-critical.

FRA also recognizes that some amendments may be purely administrative in nature. While § 270.201 subjects all changes to a SSP plan to a formal review and approval process, FRA believes that purely administrative changes should be excluded from the process so that the agency can focus its resources on more substantive matters. FRA has therefore included paragraph (c)(1)(iii) in the final rule to limit the need for formal FRA approval of purely administrative changes to previously approved SSP plans. This paragraph will allow these specific types of amendments to become effective immediately upon filing with FRA and thereby help to streamline the approval process. All other proposed amendments must comply with the formal approval process in paragraph (c) of this section.

Except as provided in paragraph (c)(1)(iii), FRA will review the proposed amended SSP plan within 45 days of receipt, under paragraph (c)(2)(i). FRA will then notify the primary contact person whether the proposed amended SSP plan has been approved by FRA. If the amended plan is not approved, FRA will provide the specific points in which each proposed amendment to the plan is deficient. If FRA does not notify the railroad whether the amended plan is approved or not by the proposed effective date of the amendment(s) to the plan, the railroad may implement the amendment(s) to the plan. This implementation, however, is subject to FRA's pending decision regarding whether the amendment is approved or not. This provision provides flexibility for railroads to implement proposed amendments pending FRA's decision, should FRA not affirmatively act within the prescribed time periods. However, should FRA not approve a proposed amendment, the railroad must follow the procedures in paragraph (c)(2)(iii) to re-implement the amendment.

If a proposed amendment to the SSP plan is not approved by FRA, the railroad has two options: Correct all deficiencies and resubmit the amendment to FRA, or provide notice to FRA that it is retracting the proposed amendment. The final rule makes clear that the railroad may retract the proposed amendment rather than correct it, whichever option it believes best. The railroad will have 60 days following receipt of FRA's written notice that any proposed amendment was not approved to either submit a corrected copy of the amendment that addresses all deficiencies noted by FRA or to submit notice that the railroad is retracting the amendment.

Paragraph (d) allows FRA to reopen consideration of a plan or amendment after initial approval of the plan or amendment. Examples of the types of cause for which FRA may reopen review include FRA's determination that the railroad is not complying with its plan or plan amendment, and FRA's awareness of material information about which FRA was unaware when it originally reviewed the plan or amendment. The determination of whether to reopen consideration will be made solely within FRA's discretion on a case-by-case basis.

FRA sought comment in the NPRM on whether electronic submission of a SSP plan should be permitted and, if so, what type of process FRA should use to accept such submissions. All of the commenters who responded to this request supported electronic submission. Therefore, paragraph (e) permits documents to be submitted electronically. To provide guidance on electronic submission, FRA added Appendix C, Procedures for Submission of System Safety Program Plans and Statements from Directly Affected Employees, which is addressed below.

Section 270.203 Retention of System Safety Program Plan

This section sets forth the requirements for a railroad's retention of its SSP plan. FRA did not receive any comments in response to this section and, therefore, it remains unchanged from the NPRM. A railroad will be required to retain at its system headquarters, and at any division headquarters, a copy of its SSP plan and a copy of any amendments to the plan. The railroad must make the plan and any amendments available to representatives of FRA and States participating under part 212 of this chapter for inspection and copying during normal business hours.

Subpart D—System Safety Program Internal Assessments and External Auditing

Subpart D sets forth the requirements for a railroad's internal SSP assessment and FRA's external audit of the railroad's SSP.

Section 270.301 General

To determine whether a SSP is successful, it will need to be evaluated by both the railroad and FRA on a periodic basis. This section sets forth the general requirement that a railroad's SSP and its implementation will be assessed internally by the railroad and audited externally by FRA or FRA's designee. FRA did not receive any comments in response to this section and, therefore, it remains unchanged from the NPRM.

Section 270.303 Internal System Safety Program Assessment.

This section sets forth the requirements for the railroad's internal SSP assessment. FRA did not receive any comments in response to this section and, therefore, it remains substantively unchanged from the NPRM. Once FRA approves a railroad's SSP plan, the railroad shall conduct an annual assessment of the extent to which: (1) The SSP is fully implemented; (2) the railroad is in compliance with the implemented elements of the approved SSP plan; and (3) the railroad has achieved the goals set forth in § 270.103(c). This internal assessment will provide the railroad with an overall survey of the progress of its SSP implementation and the areas in which improvement is necessary.

As part of its SSP plan, the railroad will describe the processes used to: (1) Conduct internal SSP assessments; (2) report the findings of the internal SSP assessments internally; (3) develop, track, and review recommendations as a result of the internal SSP assessments; (4) develop improvement plans based on the internal SSP assessments that, at a minimum, identify who is responsible for carrying out the necessary tasks to address assessment findings and specify a schedule of target dates with milestones to implement the improvements that address the assessment findings; and (5) manage revisions and updates to the SSP plan based on the internal SSP assessments. By describing these processes, the railroad will detail how it plans to assess its SSP and how it will improve it if necessary. Since this is an internal assessment, a railroad will tailor the processes to its specific operations.

FRA notes that the NPRM also proposed that the railroad would describe the process it uses to comply with the reporting requirements set forth in proposed § 270.201. However, FRA has determined that it is not necessary to adopt this proposed requirement, and it is not included in this paragraph (b).

Within 60 days of completing its internal assessment, the railroad will submit a copy of its internal assessment report to the FRA Associate Administrator for Railroad Safety and Chief Safety Officer, Mail Stop 25, 1200 New Jersey Avenue SE., Washington, DC 20590. The NPRM did not specify the individual at FRA to whom the internal assessment report will be sent, which has been clarified in the final rule. This report will include the SSP assessment and the status of internal assessment findings and improvement plans. The railroad will also outline the specific improvement plans for achieving full implementation of its SSP and the milestones it has set forth. The railroad's chief official responsible for safety shall certify the results of the railroad's internal SSP plan assessment.

Section 270.305 External Safety Audit

This section sets forth the process FRA will utilize when it conducts audits of a railroad's SSP. FRA did not receive any comments in response to this section and, therefore, it is essentially unchanged from the NPRM. These audits will evaluate the railroad's compliance with the elements required by this part in the railroad's approved SSP plan. Because this section is predicated on the railroad's SSP plan and any amendments having already been approved by FRA pursuant to § 270.201(b) and (c), this section permits FRA to focus on the extent to which the railroad is complying with its own program.

Similar to the SSP plan review process, FRA does not intend the audit to be conducted in a vacuum. Rather, during the audit, FRA will maintain communication with the railroad and attempt to resolve any issues before completion of the audit. Once the audit is completed, FRA will provide the railroad with written notification of the audit results. These results will identify any areas where the railroad is not properly complying with its SSP, any areas that need to be addressed by the SSP but are not, and any other areas in which FRA believes the railroad and its plan are not in compliance with this part.

If the results of the audit require the railroad to take any corrective action, the railroad is provided 60 days to submit for approval an improvement plan to address the audit findings. The improvement plan will identify who is responsible for carrying out the necessary tasks to address the audit findings and specify target dates and milestones to implement the improvements that address the audit findings. Specification of milestones is important because it will allow the railroad to determine the appropriate progress of the improvements while allowing FRA to gauge the railroad's compliance with its improvement plan.

If FRA does not approve a railroad's improvement plan, FRA will notify the railroad of the specific deficiencies in the improvement plan. The railroad will then amend the improvement plan to correct the deficiencies identified by FRA and provide FRA a copy of the amended improvement plan no later than 30 days after the railroad has received notice from FRA that its improvement plan was not approved. This process is similar to the process provided in § 270.201(b)(3) when FRA does not initially approve a railroad's SSP. Upon request, the railroad shall provide to FRA and States participating under part 212 of this chapter for review a report regarding the status of the implementation of the improvements set forth in the improvement plan established pursuant to paragraph (b)(1) of this section.

Appendix A to Part 270—Schedule of Civil Penalties

Appendix A to part 270 contains a schedule of civil penalties for use to enforce this part. Because such penalty schedules are statements of agency policy, notice and comment are not required before their issuance. *See* 5 U.S.C. 553(b)(3)(A). Nevertheless, FRA invited comment on the penalty schedule. However, FRA did not receive any comments other than the Labor Organizations' comment that the NPRM lacked a penalty schedule. As noted above, FRA typically does not include a penalty schedule in an NPRM. Accordingly, FRA is issuing this penalty schedule reflecting the requirements of this final rule.

Appendix B to Part 270—Federal Railroad Administration Guidance on the System Safety Program Consultation Process

Appendix B contains guidance on how a railroad could comply with § 270.107, which states that a railroad must in good faith consult with and use its best efforts to reach agreement with all of its directly affected employees on the contents of the SSP plan. The appendix begins with a general discussion of the terms "good faith" and "best efforts," explaining that they are separate terms and that each has a specific and distinct meaning. For example, the good faith obligation is concerned with a railroad's state of mind during the consultation process, and the best efforts obligation is concerned with the specific efforts made by the railroad in an attempt to reach agreement with its directly affected employees. The appendix also explains that FRA will determine a railroad's compliance with the § 270.107 requirements on a case-by-case basis and outlines the potential consequences for a railroad that fails to consult with its directly affected employees in good faith and using best efforts.

The appendix also contains specific guidance on the process a railroad may use to consult with its directly affected employees. This guidance would not establish prescriptive requirements with which a railroad must comply, but provides the road map for how a railroad may conduct the consultation process. The guidance also distinguishes between employees who are represented by a non-profit employee labor organization and employees who are not, as the processes a railroad may use to consult with represented and non-represented employees could differ significantly. Overall, however, the appendix stresses that there are many compliant ways in which a railroad may choose to consult with its directly affected employees and that FRA believes, therefore, that it is important to maintain a flexible approach to the § 270.107 consultation requirements, so a railroad and its directly affected employees may consult in the manner best suited to their specific circumstances.

Appendix C to Part 270—Procedures for Submission of System Safety Program Plans and Statements From Directly Affected Employees

Appendix C provides railroads and directly affected employees the option to file SSP plans or consultation statements electronically. As discussed above, the NPRM requested comment regarding whether electronic submission of SSP materials should be allowed. All of the comments received in response to this request supported electronic submission, and, therefore, Appendix C has been added.

FRA intends to create a secure document submission site and needs basic information from railroads or directly affected employees before setting up a user's account. To provide secure access, information regarding the points of contact is required. It is anticipated that FRA will be able to approve or disapprove all or part of a program and generate automated notifications by email to a railroad's points of contact. Thus, FRA needs each point of contact to understand that by providing any email addresses, the railroad is consenting to receive approval and disapproval notices from FRA by email. Railroads that allow notice from FRA by email gain the benefit of receiving such notices quickly and efficiently.

Those railroads that choose to submit printed materials to FRA are required to deliver them directly to the specified address. Some railroads may choose to deliver a CD, DVD, or other electronic storage format to FRA rather than requesting access to upload the documents directly to the secure electronic database. Although that is an acceptable method of submission, FRA encourages each railroad to utilize the electronic submission capabilities of the system. Of course, if FRA does not have the capability to read the type of electronic storage format sent, FRA will reject the submission.

FRA may be able to develop a secure document submission site so that confidential materials would be identified and not shared with the general public. However, FRA does not expect the information in a SSP plan to be of such a confidential or proprietary nature, particularly since each railroad is required to share the submitted SSP plan with individuals identified in the service list pursuant to § 270.107(b)(3). SSP records in FRA's possession are also exempted from disclosure under the Freedom of Information Act pursuant to section 20118, and § 270.105 protects any information compiled or collected solely for the purpose of developing, implementing, or evaluating a SSP from discovery, admission into evidence, or consideration for other purposes in a Federal or State court proceeding for damages involving personal injury, wrongful death, and property damage. Accordingly, FRA does not at this time believe it is necessary to develop a document submission system which addresses confidential materials at this time.

VII. Regulatory Impact and Notices

A. Executive Orders 12866 and 13563 and DOT Regulatory Policies and Procedures

This final rule has been evaluated under existing policies and procedures, and determined to be "Other Significant" under both Executive Orders 12866 and 13563 and DOT policies and procedures. 44 FR 11034, Feb. 26, 1979. FRA has prepared and placed in the docket a regulatory impact analysis (RIA) addressing the economic impact of this final rule.

This final rule directly responds to the Congressional mandate in section 20156(a) that FRA, by delegation from the Secretary, require each railroad that provides intercity rail passenger or commuter rail passenger transportation to establish a railroad safety risk reduction program. This final rule also implements section 20119(b), which authorizes FRA, by delegation from the Secretary, to issue a regulation protecting from discovery and admissibility into evidence in litigation documents generated for the purpose of developing, implementing, or evaluating a SSP. FRA believes that all of the requirements of this final rule are directly or implicitly required by these statutory mandates and will promote railroad safety.

Most of the 30 existing commuter and intercity passenger railroads required to comply with the final rule belong to the APTA system safety program and are currently participating in the APTA system safety triennial audit program. The rule adopts many of the elements contained in the APTA "Manual for the Development of System Safety Program Plans for Commuter Railroads." [10] The rule's costs and benefits are incremental to the APTA program. Because FRA believes all but one covered railroad follows the APTA program, FRA does not expect this rule will have significant costs. Table E–1 presents a summary of the rule's benefits and costs.

TABLE E–1—SUMMARY OF THE RULE'S COSTS AND BENEFITS

		Undiscounted	Discounted at 7 percent	Discounted at 3 percent
Estimated Costs	Over 20-years	[11] $4,743,039	$2,327,224	$3,412,651
	Annualized	237,152	219,674	229,384
Cost From Risk Analyses and Risk Mitigation		Not estimated, as FRA lacks information to reliably estimate such costs, and it does not know the level of hazards and risks on each railroad and means railroads will use to mitigate.		
Benefits		Not estimated but expected to include safety improvements and operational efficiencies resulting primarily from more robust SSPs, additional and improved risk analysis and mitigation, better information about systems, and improved safety culture.		

The SSP NPRM RIA was performed on a breakeven basis. FRA modified that approach in this final rule because FRA could not estimate all relevant regulatory costs, namely those resulting from risk analysis and risk mitigation. These costs are not reasonably predictable until data protections are in place and each railroad produces and implements their SSP plans assessing their hazards and risk levels. Nevertheless, the pool of potential safety benefits is large as evidenced by the number of accidents and incidents experienced on passenger railroads this rule could impact. FRA expects railroads will achieve sufficient safety benefits to justify quantified and unquantified costs.

Costs

The rule has requirements in addition to those in the APTA program. FRA estimated the rule's costs for those additional requirements which include: Documenting the SSP plan and the safety certification process; SSP training; preparing for and providing information in response to external audits; providing mitigation method information to FRA; preparing technology analysis results and providing them to FRA; providing an annual assessment of SSP performance and improvement plans; consulting with directly affected employees and preparing consultation statements; amending SSP plans; retaining records; and conducting internal SSP assessments. (Table E–1 above summarizes these costs.) FRA did not estimate the full incremental costs of railroads conducting additional and more robust hazard and risk analysis or implementing actions to mitigate identified hazards and risks. FRA lacks information to reliably estimate such costs, as it does not know the level of hazards and risks on each railroad and the means railroads will use to mitigate these risks.

Benefits

FRA could not estimate the final rule's full benefits quantitatively as SSPs are primarily an organizational structure and program to manage safety through hazard analysis and mitigation. FRA cannot accurately estimate the rule's incremental safety benefits because FRA cannot reliably predict the specific risks each railroad will identify or the specific actions they will take to mitigate such risks relative to the APTA program. For these reasons, FRA assessed the rule's benefits qualitatively. FRA expects that safety and operational benefits will result from mechanisms in the rule leading to improved safety analysis and risk mitigation, including (1) requirements to demonstrate a robust SSP to FRA, (2) requirements designed to improve safety culture, and (3) protection of certain SSP information. Railroad management and employees will have to achieve the safety goals in their SSPs, but there will also be FRA oversight to monitor and require corrective actions if and when necessary.

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[10] *http://www.apta.com/resources/reportsandpublications/Documents/commuter_rail_manual.pdf* (last accessed on March 22, 2016).

[11] The NPRM estimated the costs of the proposed rule to be $4.1 million. FRA estimates the final rule's costs are $4.7 million, a nominal increase of $620,000 (14.6 percent). The cost estimate increased from the NPRM to the final rule due to the following: (1) Application of the Congressional Budget Office real wage forecasts for each year of the analysis; (2) updating the wage inputs used to account for the Surface Transportation Board's newest wage rates for 2012 and a 2015 base year; and (3) an adjustment to allow more time for railroad consultation with directly affected employees and statement preparation. (The consultation time with labor and affected employees is $135,000 of the $620,000 total.) See: *http://www.dot.gov/regulations/economic-values-used-in analysis* (DOT's guidance on Value of a Statistical Life (VSL)). (The VSL was further updated June 17, 2015 to $9.4 million.).

Congress directed FRA to conduct a study to determine if it was in the public interest to withhold certain information from discovery and admission into evidence in Federal or State court proceedings for damages involving personal injury and wrongful death, including the railroad's assessment of its safety risks and its mitigation measures. FRA contracted with an outside organization to conduct this study and the study concluded it was in the public interest to withhold this type of information from these types of proceedings. Thus, the rule sets forth protections of certain SSP information from discovery, admission into evidence, or use for other purposes in a proceeding for damages. FRA expects the information protections will result in railroads conducting more robust risk-based hazard analysis, keeping more detailed records of hazards and risks, and implementing additional actions to mitigate safety risks. FRA could not estimate the costs of the information protections or the resulting incremental safety risk analysis and mitigation activities, but believes they are justified by the resultant safety improvements' benefits.

In conclusion, FRA determined the final rule's benefits justify its costs. To illustrate, FRA estimated the total cost of passenger railroad accidents/incidents is $33 billion (discounted at 7 percent) and $51 billion (discounted at 3 percent) over a 20-year future period. These costs show the potential pool of safety benefits this rule can impact is very large, especially compared to the rule's quantified costs. FRA expects railroads will implement the most cost-effective mitigations to eliminate or mitigate hazards. Railroads are not required to implement mitigations with net costs and FRA expects that railroads will implement mitigations with net benefits. FRA expects railroads can achieve sufficient safety benefits to justify both the costs FRA could estimate and those it could not.

B. Regulatory Flexibility Act and Executive Order 13272

FRA developed the final rule under Executive Order 13272 ("Proper Consideration of Small Entities in Agency Rulemaking") and DOT's procedures and policies to promote compliance with the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) to ensure potential impacts of rules on small entities are properly considered.

The Regulatory Flexibility Act (RFA) requires an agency to review regulations to assess their impact on small entities. An agency must conduct a regulatory flexibility analysis unless it determines and certifies that a rule is not expected to have a significant economic impact on a substantial number of small entities.

FRA conducted an Initial Regulatory Impact Analysis (IRFA) pursuant to the Regulatory Flexibility Act (5 U.S.C. 605(b)) for the SSP NPRM. 77 FR 55397–99, Sept. 7, 2012. Furthermore, FRA invited all interested parties to submit data and information regarding this certification. The comments received are addressed below. FRA certifies that this final rule would not have a significant economic impact on a substantial number of small entities. Although a substantial number of small railroads would be affected by this final rule, none would be significantly impacted.

1. Description of Regulated Entities and Impacts

The "universe" of the entities under consideration includes only those small entities that can reasonably be expected to be directly affected by the provisions of this final rule. For this final rule there is only one type of small entity that is affected: Small railroads.

"Small entity" is defined in 5 U.S.C. 601. Section 601(6) defines "small entity" as having "the same meaning as the terms 'small business', 'small organization' and 'small governmental jurisdiction' " as defined by section 601. Section 601(3) defines "small business" as having the same meaning as "small business concern" under section 3 of the Small Business Act. Section 601(4) defines "small organization" as "any not-for-profit enterprise which is independently owned and operated and is not dominant in its field." Section 601(5) defines "small governmental jurisdiction" as "governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand."

The U.S. Small Business Administration (SBA) stipulates "size standards" for small entities. It provides that the largest a for-profit railroad business firm may be (and still classify as a "small entity") is 1,500 employees for "Line-Haul Operating" railroads, and 500 employees for "Short-Line Operating" railroads.[12]

Federal agencies may adopt their own size standards for small entities in consultation with SBA, and in conjunction with public comment. Pursuant to the authority provided to it by SBA, FRA has published a final policy, which formally establishes small entities as railroads that meet the line haulage revenue requirements of a Class III railroad.[13] FRA used this definition for this rule making in preparation of the proposed rule along with the stipulation on government entities or agencies that serve small communities as stated above.

Passenger and Commuter Railroads

Commuter and intercity passenger railroads will have to comply with all provisions of part 270; however, the amount of effort to comply with this rule is commensurate with the size of the entity.

For purposes of this analysis, FRA analyzed two intercity passenger railroads, Amtrak and the Alaska Railroad.[14] Neither is considered a small entity. Amtrak is a Class I railroad and the Alaska Railroad is a Class II railroad. The Alaska Railroad is owned by the State of Alaska, which has a population well in excess of 50,000.

There are 28 commuter or other short-haul passenger railroad operations in the U.S. Most of these commuter railroads are part of larger transit organizations that receive Federal funds and serve major metropolitan areas with populations greater than 50,000. However, two of these railroads do not fall in this category and are considered small entities: Saratoga & North Creek Railway (SNC) and the Hawkeye Express (operated by the Iowa Northern Railway Company (IANR)). All other passenger railroad operations in the United States are part of larger governmental entities, whose service jurisdictions exceed 50,000 in population, and based on the definition, they are not considered to be small entities.

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[12] "Table of Size Standards," U.S. Small Business Administration, January 31, 1996, 13 CFR part 121.

[13] See 68 FR 24891, May 9, 2003.

[14] There are state-sponsored intercity passenger rail services, the vast majority of which will be part of Amtrak's SSP.

Significant Economic Impact Criteria

FRA estimates that the total cost for the final rule will be $4.7 million (undiscounted)—$2.3 million (discounted at 7 percent), or $3.4 million (discounted at 3 percent), for the railroad industry over a 20-year period. The cost burden to the two small entities will be considerably less on average than that of the other 28 railroads. FRA estimates impacts on these two railroads could range on average between $1,590 and $3,346 annualized (non-discounted) to comply with the regulation, depending on the existing level of compliance and discount rate. This estimate was prepared and presented in the IRFA for the NPRM and adjusted in the final rule for revised cost factors applied in the Regulatory Impact Analysis, *e.g.* inflating wages and salaries at 1.07 percent per annum.

Since the time that the NPRM IRFA was prepared, both of the two small entities herein have produced preliminary SSP plans. That plan preparation, with the assistance of FRA and others, will have accomplished much of the work effort envisioned for preparing the formal SSP Plans once the Rule is in effect.

Based on this, FRA concludes that the expected burden of this final rule will not have a significant impact on the competitive position of small entities, or on the small entity segment of the railroad industry as a whole.

Substantial Number Criteria

This final rule will likely burden only two small railroads; however, this is two out of 30 total railroads impacted by this Rule, and two out of two small railroads. Thus, as noted above, this final rule will impact a substantial number of small railroads.

Public Comments and Revisions to the Analysis

The final rule is a performance-based rule and the NPRM, and the regulatory evaluation for the NPRM, requested comments and input on the rulemaking and its supporting documents. The following provides a summary of the comments received that pertained to RFA for small businesses, and how those comments were addressed. FRA did not receive any comments from SBA.

APTA commented that they "believe FRA has applied faulty criteria in determining only two railroads should be treated as small entities." FRA determined that there would be only two passenger railroads affected by the SSP rulemaking as small entities. In applying the guidelines of RFA, FRA includes most Class III railroads impacted by a rule as a small business. Only one railroad that will be governed under this final rule is a Class III railroad. RFA guidelines also indicate that if the entity is a part of or agent of governments of cities, counties, towns, townships, villages, or special districts serving a population of more than 50,000, they would not be classified as a small business. Essentially all, except the two railroads FRA classified as small businesses, are a governmental related transportation agency serving population areas of 50,000 or more or an intercity service provider (Amtrak and Alaska), or both.[15] (The definition, SBA based, of small entity that FRA used in the IRFA, results in only two entities considered to be small.)

APTA also suggested that FRA should ensure "that this proposed rule's requirements are commensurate to the size of the entity" and "compliance with this proposed rule should include flexibility, scalability, and program maturity as relevant factors to determine whether a program is 'fully implemented.'" FRA does expect the structure and scope of a SSP will be commensurate with the size and maturity of the entity. FRA has regularly provided assistance to both new and smaller passenger entities, including the two small entities considered herein, with setting up their safety programs, and with approaches to hazard and risk management. FRA will continue to provide that assistance in the plan development phase of preparing their SSP Plans. The SSP regulation provides a scalable approach that will be easier to implement on a small railroad.

2. Certification

Pursuant to the Regulatory Flexibility Act (5 U.S.C. 605(b)), FRA certifies that this final rule will not have a significant economic impact on a substantial number of small entities. FRA invited all interested parties to submit data and information regarding the potential economic impact that will result from adoption of the proposals in the NPRM and has addressed those comments in determining that although a substantial number of small railroads will be affected by this final rule, none of these entities will be significantly impacted.

C. Federalism

Executive Order 13132, "Federalism" (64 FR 43255, Aug. 10, 1999), requires FRA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" are defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." Under Executive Order 13132, the agency may not issue a regulation with federalism implications that imposes substantial direct compliance costs and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments or the agency consults with State and local government officials early in the process of developing the regulation. Where a regulation has federalism implications and preempts State law, the agency seeks to consult with State and local officials in the process of developing the regulation.

This final rule has been analyzed under the principles and criteria in Executive Order 13132. FRA has determined that this rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. In addition, FRA has determined that this rule does not impose substantial direct compliance costs on State and local governments. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

This rule adds part 270, System Safety Program. FRA notes that this part could have preemptive effect by the operation of law under a provision of the former Federal Railroad Safety Act of 1970, repealed and codified at 49 U.S.C. 20106 (Sec. 20106). Sec. 20106 provides that States may not adopt or continue in effect any law, regulation, or order related to railroad safety or security that covers the subject matter of a regulation prescribed or order issued by the Secretary of Transportation (with respect to railroad safety matters) or the Secretary of Homeland Security (with respect to railroad security matters), except when the State law, regulation, or order qualifies under the "essentially local safety or security hazard'' exception to Sec. 20106. FRA has determined that certain State laws may be preempted by this part. FRA is aware of one State that has a State Safety Oversight program pursuant to 49 CFR part 659 that has certain elements that will be preempted by part 270. Further, § 270.105(d) specifically addresses the preemption of State discovery rules and sunshine laws to the extent those laws would require disclosure of information protected by § 270.105 in a Federal or State court proceedings for damages involving personal injury, wrongful death, or property damage. The preemption of State discovery rules and sunshine laws are discussed further in the section-by-section analysis of § 270.105(d). In addition, as previously discussed, section 20119(b) authorizes FRA to issue a rule governing the discovery and use of risk analysis information in litigation.

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[15] Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*): "Small governmental jurisdictions" are governments of cities, counties, towns, townships, villages, school districts, or special districts with a population of less than 50,000.

In sum, FRA has analyzed this proposed rule under the principles and criteria in Executive Order 13132. As explained above, FRA has determined that this proposed rule has minimal federalism implications. Accordingly, FRA has determined that preparation of a federalism summary impact statement for this proposed rule is not required.

D. International Trade Impact Assessment

The Trade Agreement Act of 1979 prohibits Federal agencies from engaging in any standards or related activities that create unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic objectives, such as safety, are not considered unnecessary obstacles. The statute also requires consideration of international standards and where appropriate, that they be the basis for U.S. standards. This rulemaking is purely domestic in nature and is not expected to affect trade opportunities for U.S. firms doing business overseas or for foreign firms doing business in the United States.

E. Paperwork Reduction Act

The information collection requirements in this final rule are being submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.* The sections that contain the new information collection requirements are duly designated, and the estimated time to fulfill each requirement is as follows:

CFR Section/Subject	Respondent universe	Total annual responses	Average time per response	Total annual burden hours
270.103—System Safety Program Plan (SSPP)—Comprehensive Written SSPP Meeting All of This Section's Requirements.	30 railroads	30 plans	40 hours (32 hrs. for plan + 8 hrs. review).	1,200
—System Safety Training by RR of Employees/Contractors/Others.	30 railroads	450 trained individuals	2 hours	900
—Records of System Safety Trained Employees/Contractors/Others.	30 railroads	450 records	2 minutes	15
—Furnishing of RR Results of Risk-based Hazard Analysed Upon FRA/Participating Part 212 States.	30 railroads	10 analyses results	20 hours	200
—Furnishing of Descriptions of Railroad's Specific Risk Mitigation Methods That Address Hazards Upon FRA Request.	30 railroads	10 mitigation methods descriptions.	10 hours	100
—Furnishing of Results of Railroad's Technology Analysis Upon FRA/Participating Part 212 States' Request.	30 railroads	30 results of technology analysis.	40 hours	1,200
270.107(a)—Consultation Requirements—RR Consultation with Its Directly Affected Employees on System Safety Program Plan (SSPP).	30 railroads	30 consults (w/labor union reps.).	40 hours	1,200
—RR Notification to Directly Affected Employees of Preliminary Meeting at Least 60 Days Before Being Held.	30 railroads	30 notices	8 hours	240
—(b) RR Consultation Statements	30 railroads	28 statements + 2 statement.	80 hours + 2 hours	2,244
—Copies of Consultations Statements by RR to Service List Individuals.	30 railroads	30 copies	1 minute	1
270.201—SSPPs Found Deficient by FRA and Requiring Amendment.	30 railroads	4 amended plans	40 hours	160
—Review of Amended SSPPs Found Deficient and Requiring Amendment.	30 railroads	1 amended plans	40 hours	40
—Reopened Review of Initial SSPP Approval For Cause Stated.	30 railroads	2 amended plans	40 hours	80
270.203—Retention of SSPPs	30 railroads	37 copies	10 minutes	6
— Retained copies of SSPPs				
270.303—Annual Internal SSPP Assessments/Reports Conducted by RRs.	30 railroads	30 evaluation reports	40 hours	1,200
—Certification of Results of RR Internal Assessment by Chief Safety Official.	30 railroads	30 statements	8 hours	240
270.305—External Safety Audit	30 railroads	6 plans	40 hours	240
—RR Submission of Improvement Plans in Response to Results of FRA Audit.				
—Improvement Plans Found Deficient by FRA and Requiring Amendment.	30 railroads	2 amended plans	24 hours	48
—RR Status Report to FRA of Implementation of Improvements Set Forth in the Improvement Plan.	30 railroads	2 reports	4 hours	8
Appendix B—Additional Documents Provided to FRA Upon Request.	30 railroads	2 documents	30 minutes	1

CFR Section/Subject	Respondent universe	Total annual responses	Average time per response	Total annual burden hours
—Notifications/Good Faith Consultation with Non-Represented Employees by RRs.	2 railroads	2 notices/consults	8 hours	16
—Meeting with Non-Represented Employees within 180 Days of Final Rule Effective Date About Consultation Process.	2 railroads	2 meetings	8 hours	16
Appendix C—Written Requests by RRs to File Required Submissions Electronically.	30 railroads	20 written requests	30 minutes	10
Totals	30 railroads	1,240 replies/responses	6.832 hours	9,365

All estimates include the time for reviewing instructions; searching existing data sources; gathering or maintaining the needed data; and reviewing the information. For information or a copy of the paperwork package submitted to OMB, contact Mr. Robert Brogan at 202–493–6292 or Ms. Kimberly Toone at 202–493–6132 or via email at the following addresses: *Robert.Brogan@dot.gov;* or *Kim.Toone@dot.gov.*

Organizations and individuals desiring to submit comments on the collection of information requirements should direct them to the Office of Management and Budget, Office of Information and Regulatory Affairs, Washington, DC 20503, Attention: FRA Desk Officer. Comments may also be sent via email to the Office of Management and Budget at the following address: *oira_submissions@omb.eop.gov*

OMB is required to make a decision concerning the collection of information requirements contained in this final rule between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication.

FRA is not authorized to impose a penalty on persons for violating information collection requirements which do not display a current OMB control number, if required. FRA intends to obtain current OMB control numbers for any new information collection requirements resulting from this rulemaking action prior to the effective date of the final rule. The OMB control number, when assigned, will be announced by separate notice in the **Federal Register**.

F. Environmental Assessment

FRA has evaluated this rule under its ''Procedures for Considering Environmental Impacts'' (FRA's Procedures) (64 FR 28545, May 26, 1999) as required by the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*), other environmental statutes, Executive Orders, and related regulatory requirements. FRA has determined that this rule is not a major FRA action (requiring the preparation of an environmental impact statement or environmental assessment) because it is categorically excluded from detailed environmental review pursuant to section 4(c)(20) of FRA's Procedures. *See* 64 FR 28547, May 26, 1999. Section 4(c)(20) reads as follows: ''(c) Actions categorically excluded. Certain classes of FRA actions have been determined to be categorically excluded from the requirements of these Procedures as they do not individually or cumulatively have a significant effect on the human environment. * * * The following classes of FRA actions are categorically excluded:

* * * (20) Promulgation of railroad safety rules and policy statements that do not result in significantly increased emissions or air or water pollutants or noise or increased traffic congestion in any mode of transportation.''

Consistent with section 4(c) and (e) of FRA's Procedures, the agency has further concluded that no extraordinary circumstances exist with respect to this regulation that might trigger the need for a more detailed environmental review. As a result, FRA finds that this rule is not a major Federal action significantly affecting the quality of the human environment.

G. Unfunded Mandates Reform Act of 1995

Pursuant to section 201 of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4, 2 U.S.C. 1531), each Federal agency ''shall, unless otherwise prohibited by law, assess the effects of Federal regulatory actions on State, local, and tribal governments, and the private sector (other than to the extent that such regulations incorporate requirements specifically set forth in law).'' Section 202 of the Act (2 U.S.C. 1532) further requires that ''before promulgating any general notice of proposed rulemaking that is likely to result in the promulgation of any rule that includes any Federal mandate that may result in expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year, and before promulgating any final rule for which a general notice of proposed rulemaking was published, the agency shall prepare a written statement'' detailing the effect on State, local, and tribal governments and the private sector. For the year 2015, this monetary amount of $100,000,000 has been adjusted to $156,000,000 to account for inflation. This final rule will not result in the expenditure of more than $156,000,000 by the public sector in any one year, and thus preparation of such a statement is not required.

H. Energy Impact

Executive Order 13211 requires Federal agencies to prepare a Statement of Energy Effects for any ''significant energy action.'' 66 FR 28355, May 22, 2001. Under the Executive Order, a ''significant energy action'' is defined as any action by an agency (normally published in the **Federal Register**) that promulgates, or is expected to lead to the promulgation of, a final rule or regulation (including a notice of inquiry, advance notice of proposed rulemaking, and notice of proposed rulemaking) that (1)(i) is a significant regulatory action under Executive Order 12866 or any successor order and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (2) is designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. FRA has evaluated this rule under Executive Order 13211. FRA has determined that this rule will not have a significant adverse effect on the supply, distribution, or use of energy. Consequently, FRA has determined that this regulatory action is not a ''significant energy action'' within the meaning of Executive Order 13211.

I. Privacy Act

Interested parties should be aware that anyone is able to search the electronic form of all comments received into any agency docket by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you may visit *http://www.transportation.gov/privacy.html.*

List of Subjects in 49 CFR Part 270

Penalties; Railroad safety; Reporting and recordkeeping requirements; and System safety.

The Rule

■ In consideration of the foregoing, FRA adds part 270 to Chapter II, Subtitle B of Title 49, Code of Federal Regulations, to read as follows:

PART 270—SYSTEM SAFETY PROGRAM

Subpart A—General

Sec.

270.1 Purpose and scope.
270.3 Application.
270.5 Definitions.
270.7 Penalties and responsibility for compliance.

Subpart B—System Safety Program Requirements

270.101 System safety program; general.
270.103 System safety program plan.
270.105 Discovery and admission as evidence of certain information.
270.107 Consultation requirements.

Subpart C—Review, Approval, and Retention of System Safety Program Plans

270.201 Filing and approval.
270.203 Retention of system safety program plan.

Subpart D—System Safety Program Internal Assessments and External Auditing

270.301 General.
270.303 Internal system safety program assessment.
270.305 External safety audit.
Appendix A to Part 270—Schedule of Civil Penalties
Appendix B to Part 270—Federal Railroad Administration Guidance on the System Safety Program Consultation Process
Appendix C to Part 270—Procedures for Submission of SSP Plans and Statements from Directly Affected Employees

Authority: 49 U.S.C. 20103, 20106–20107, 20118–20119, 20156, 21301, 21304, 21311; 28 U.S.C. 2461, note; and 49 CFR 1.89.

Subpart A—General

§ 270.1 Purpose and scope.

(a) The purpose of this part is to improve railroad safety through structured, proactive processes and procedures developed and implemented by railroads. This part requires certain railroads to establish a system safety program that systematically evaluates railroad safety hazards and the resulting risks on their systems and manages those risks to reduce the number and rates of railroad accidents, incidents, injuries, and fatalities.

(b) This part prescribes minimum Federal safety standards for the preparation, adoption, and implementation of railroad system safety programs. This part does not restrict railroads from adopting and enforcing additional or more stringent requirements not inconsistent with this part.

(c) This part prescribes the protection of information generated solely for the purpose of planning, implementing, or evaluating a system safety program under this part.

§ 270.3 Application.

(a) Except as provided in paragraph (b) of this section, this part applies to all—

(1) Railroads that operate intercity or commuter passenger train service on the general railroad system of transportation; and

(2) Railroads that provide commuter or other short-haul rail passenger train service in a metropolitan or suburban area (as described by 49 U.S.C. 20102(2)), including public authorities operating passenger train service.

(b) This part does not apply to:

(1) Rapid transit operations in an urban area that are not connected to the general railroad system of transportation;

(2) Tourist, scenic, historic, or excursion operations, whether on or off the general railroad system of transportation;

(3) Operation of private cars, including business/office cars and circus trains; or

(4) Railroads that operate only on track inside an installation that is not part of the general railroad system of transportation (*i.e.,* plant railroads, as defined in § 270.5).

§ 270.5 Definitions.

As used in this part—

Administrator means the Federal Railroad Administrator or his or her delegate.

Configuration management means a process that ensures that the configurations of all property, equipment, and system design elements are accurately documented.

FRA means the Federal Railroad Administration.

Fully implemented means that all elements of a system safety program as described in the SSP plan are established and applied to the safety management of the railroad.

Hazard means any real or potential condition (as identified in the railroad's risk-based hazard analysis) that can cause injury, illness, or death; damage to or loss of a system, equipment, or property; or damage to the environment.

Passenger means a person, excluding an on-duty employee, who is on board, boarding, or alighting from a rail vehicle for the purpose of travel.

Person means an entity of any type covered under 1 U.S.C. 1, including, but not limited to, the following: a railroad; a manager, supervisor, official, or other employee or agent of a railroad; any owner, manufacturer, lessor, or lessee of railroad equipment, track, or facilities; any independent contractor or subcontractor providing goods or services to a railroad; and any employee of such owner, manufacturer, lessor, lessee, or independent contractor or subcontractor.

Plant railroad means a plant or installation that owns or leases a locomotive, uses that locomotive to switch cars throughout the plant or installation, and is moving goods solely for use in the facility's own industrial processes. The plant or installation could include track immediately adjacent to the plant or installation if the plant railroad leases the track from the general system railroad and the lease provides for (and actual practice entails) the exclusive use of that trackage by the plant railroad and the general system railroad for purposes of moving only cars shipped to or from the plant. A plant or installation that operates a locomotive to switch or move cars for other entities, even if solely within the confines of the plant or installation, rather than for its own purposes or industrial processes, is not considered a plant railroad because the performance of such activity makes the operation part of the general railroad system of transportation.

Positive train control system means a system designed to prevent train-to-train collisions, overspeed derailments, incursions into established work zone limits, and the movement of a train through a switch left in the wrong position, as described in subpart I of part 236 of this chapter.

Rail vehicle means railroad rolling stock, including, but not limited to, passenger and maintenance vehicles.

Railroad means—

(1) Any form of non-highway ground transportation that runs on rails or electromagnetic guideways, including—

(i) Commuter or other short-haul rail passenger service in a metropolitan or suburban area and commuter railroad service that was operated by the Consolidated Rail Corporation on January 1, 1979; and

(ii) High speed ground transportation systems that connect metropolitan areas, without regard to whether those systems use new technologies not associated with traditional railroads, but does not include rapid transit operations in an urban area that are not connected to the general railroad system of transportation; and

(2) A person or organization that provides railroad transportation, whether directly or by contracting out operation of the railroad to another person.

Risk means the combination of the probability (or frequency of occurrence) and the consequence (or severity) of a hazard.

Risk-based hazard management means the processes (including documentation) used to identify and analyze hazards, assess and rank corresponding risks, and eliminate or mitigate the resulting risks.

Safety culture means the shared values, actions and behaviors that demonstrate commitment to safety over competing goals and demands.

SSP plan means system safety program plan.

System safety means the application of management, economic, and engineering principles and techniques to optimize all aspects of safety, within the constraints of operational effectiveness, time, and cost, throughout all phases of a system life cycle.

System safety program means a comprehensive process for the application of management and engineering principles and techniques to optimize all aspects of safety.

System safety program plan means a document developed by the railroad that implements and supports the railroad's system safety program.

Tourist, scenic, historic, or excursion operations means railroad operations that carry passengers, often using antiquated equipment, with the conveyance of the passengers to a particular destination not being the principal purpose. Train movements of new passenger equipment for demonstration purposes are not tourist, scenic, historic, or excursion operations.

§ 270.7 Penalties and responsibility for compliance.

(a) Any person who violates any requirement of this part or causes the violation of any such requirement is subject to a civil penalty of at least $839 and not more than $27,455 per violation, except that: Penalties may be assessed against individuals only for willful violations, and, where a grossly negligent violation or a pattern of repeated violation has created an imminent hazard of death or injury to persons, or has caused death or injury, a penalty not to exceed $109,819 per violation may be assessed. Each day a violation continues shall constitute a separate offense. Any person who knowingly and willfully falsifies a record or report required by this part may be subject to criminal penalties under 49 U.S.C. 21311 (formerly codified in 45 U.S.C. 438(e)). Appendix A to this part contains a schedule of civil penalty amounts used in connection with this part.

(b) Although the requirements of this part are stated in terms of the duty of a railroad, when any person, including a contractor or subcontractor to a railroad, performs any function covered by this part, that person (whether or not a railroad) shall perform that function in accordance with this part.

Subpart B—System Safety Program Requirements

§ 270.101 System safety program; general.

(a) Each railroad subject to this part shall establish and fully implement a system safety program that continually and systematically evaluates railroad safety hazards on its system and manages the resulting risks to reduce the number and rates of railroad accidents, incidents, injuries, and fatalities. A system safety program shall include a risk-based hazard management program and risk-based hazard analysis designed to proactively identify hazards and mitigate or eliminate the resulting risks. The system safety program shall be fully implemented and supported by a written SSP plan described in § 270.103.

(b) A railroad's system safety program shall be designed so that it promotes and supports a positive safety culture at the railroad.

§ 270.103 System safety program plan.

(a) *General.* (1) Each railroad subject to this part shall adopt and fully implement a system safety program through a written SSP plan that, at a minimum, contains the elements in this section. This SSP plan shall be approved by FRA under the process specified in § 270.201.

(2) Each railroad subject to this part shall communicate with each railroad that hosts passenger train service for that railroad and coordinate the portions of the SSP plan applicable to the railroad hosting the passenger train service.

(b) *System safety program policy statement.* Each railroad shall set forth in its SSP plan a policy statement that endorses the railroad's system safety program. This policy statement shall:

(1) Define the railroad's authority for the establishment and implementation of the system safety program;

(2) Describe the safety philosophy and safety culture of the railroad; and

(3) Be signed by the chief official at the railroad.

(c) *System safety program goals.* Each railroad shall set forth in its SSP plan a statement defining the goals for the railroad's system safety program. This statement shall describe clear strategies on how the goals will be achieved and what management's responsibilities are to achieve them. At a minimum, the goals shall be:

(1) Long-term;

(2) Meaningful;

(3) Measurable; and

(4) Focused on the identification of hazards and the mitigation or elimination of the resulting risks.

(d) *Railroad system description.* (1) Each railroad shall set forth in its SSP plan a statement describing the railroad's system. The description shall include: the railroad's operations, including any host operations; the physical characteristics of the railroad; the scope of service; the railroad's maintenance activities; and any other pertinent aspects of the railroad's system.

(2) Each railroad shall identify the persons that enter into a contractual relationship with the railroad to either perform significant safety-related services on the railroad's behalf or to utilize significant safety-related services provided by the railroad for purposes related to railroad operations.

(3) Each railroad shall describe the relationships and responsibilities between the railroad and: host railroads, contract operators, shared track/corridor operators, and persons providing or utilizing significant safety-related services as identified by the railroad pursuant to paragraph (d)(2) of this section.

(e) *Railroad management and organizational structure.* Each railroad shall set forth a statement in its SSP plan that describes the management and organizational structure of the railroad.

This statement shall include the following:

(1) A chart or other visual representation of the organizational structure of the railroad;

(2) A description of the railroad's management responsibilities within the system safety program;

(3) A description of how safety responsibilities are distributed within the railroad organization;

(4) Clear identification of the lines of authority used by the railroad to manage safety issues; and

(5) A description of the roles and responsibilities in the railroad's system safety program for each host railroad, contract operator, shared track/corridor operator, and any persons utilizing or providing significant safety-related services as identified by the railroad pursuant to (d)(2) of this section. As part of this description, the railroad shall describe how each host railroad, contractor operator, shared track/corridor operator, and any persons utilizing or providing significant safety-related services as identified by the railroad pursuant to paragraph (d)(2) of this section supports and participates in the railroad's system safety program, as appropriate.

(f) *System safety program implementation process.* (1) Each railroad shall set forth a statement in its SSP plan that describes the process the railroad will use to implement its system safety program. As part of the railroad's implementation process, the railroad shall describe:

(i) Roles and responsibilities of each position that has significant responsibility for implementing the system safety program, including those held by employees and other persons utilizing or providing significant safety-related services as identified by the railroad pursuant to (d)(2) of this section; and

(ii) Milestones necessary to be reached to fully implement the program.

(2) A railroad's system safety program shall be fully implemented within 36 months of FRA's approval of the SSP plan pursuant to subpart C of this part.

(g) *Maintenance, repair, and inspection program.* (1) Each railroad shall identify and describe in its SSP plan the processes and procedures used for maintenance and repair of infrastructure and equipment directly affecting railroad safety. Examples of infrastructure and equipment that directly affect railroad safety include: Fixed facilities and equipment, rolling stock, signal and train control systems, track and right-of-way, passenger train/station platform interface (gaps), and traction power distribution systems.

(2) Each description of the processes and procedures used for maintenance and repair of infrastructure and equipment directly affecting safety shall include the processes and procedures used to conduct testing and inspections of the infrastructure and equipment.

(3) If a railroad has a manual or manuals that comply with all applicable Federal regulations and that describe the processes and procedures that satisfy this section, the railroad may reference those manuals in its SSP plan. FRA approval of a SSP plan that contains or references such manuals is not approval of the manuals themselves; each manual must independently comply with applicable regulations and is subject to a civil penalty if not in compliance with applicable regulations.

(4) The identification and description required by this section of the processes and procedures used for maintenance, repair, and inspection of infrastructure and equipment directly affecting railroad safety is not intended to address and should not include procedures to address employee working conditions that arise in the course of conducting such maintenance, repair, and inspection of infrastructure and equipment directly affecting railroad safety as set forth in the plan. FRA does not intend to approve any specific portion of a SSP plan that relates exclusively to employee working conditions.

(h) *Rules compliance and procedures review.* Each railroad shall set forth a statement describing the processes and procedures used by the railroad to develop, maintain, and comply with the railroad's rules and procedures directly affecting railroad safety and to comply with the applicable railroad safety laws and regulations found in this chapter. The statement shall identify:

(1) The railroad's operating and safety rules and maintenance procedures that are subject to review under this chapter;

(2) Techniques used to assess the compliance of the railroad's employees with the railroad's operating and safety rules and maintenance procedures, and applicable railroad safety laws and regulations; and

(3) Techniques used to assess the effectiveness of the railroad's supervision relating to the compliance with the railroad's operating and safety rules and maintenance procedures, and applicable railroad safety laws and regulations.

(i) *System safety program employee/contractor training.* (1) Each employee who is responsible for implementing and supporting the system safety program, and any persons utilizing or providing significant safety-related services will be trained on the railroad's system safety program.

(2) Each railroad shall establish and describe in its SSP plan the railroad's system safety program training plan. A system safety program training plan shall set forth the procedures by which employees that are responsible for implementing and supporting the system safety program, and any persons utilizing or providing significant safety-related services will be trained on the railroad's system safety program. A system safety program training plan shall help ensure that all personnel who are responsible for implementing and supporting the system safety program understand the goals of the program, are familiar with the elements of the program, and have the requisite knowledge and skills to fulfill their responsibilities under the program.

(3) For each position identified pursuant to paragraph (f)(1)(i) of this section, the training plan shall describe the frequency and content of the system safety program training that the position receives.

(4) If a position is not identified under paragraph (f)(1)(i) of this section as having significant responsibility to implement the system safety program but the position is safety-related or has a significant impact on safety, personnel in those positions shall receive training in basic system safety concepts and the system safety implications of their position.

(5) Training under this subpart may include, but is not limited to, classroom, computer-based, or correspondence training.

(6) The railroad shall keep a record of all training conducted under this part and update that record as necessary. The system safety program training plan shall set forth the process used to maintain and update the necessary training records required by this part.

(7) The system safety program training plan shall set forth the process used by the railroad to ensure that it is complying with the training requirements set forth in the training plan.

(j) *Emergency management.* Each railroad shall set forth a statement in its SSP plan that describes the processes used by the railroad to manage emergencies that may arise within its system including, but not limited to, the processes to comply with applicable emergency equipment standards in part 238 of this chapter and the passenger train emergency preparedness requirements in part 239 of this chapter.

(k) *Workplace safety.* Each railroad shall set forth a statement in its SSP plan that describes the programs established by the railroad that protect the safety of the railroad's employees and contractors. The statement shall include a description of:

(1) The processes that help ensure the safety of employees and contractors while working on or in close proximity to the railroad's property as described in paragraph (d) of this section;

(2) The processes that help ensure that employees and contractors understand the requirements established by the railroad pursuant to paragraph (f)(1) of this section;

(3) Any fitness-for-duty programs or any medical monitoring programs; and

(4) The standards for the control of alcohol and drug use in part 219 of this chapter.

(l) *Public safety outreach program.* Each railroad shall establish and set forth a statement in its SSP plan that describes its public safety outreach program to provide safety information to railroad passengers and the general public. Each railroad's safety outreach program shall provide a means for railroad passengers and the general public to report any observed hazards.

(m) *Accident/incident reporting and investigation.* Each railroad shall set forth a statement in its SSP plan that describes the processes that the railroad uses to receive notification of accidents/incidents, investigate and report those accidents/incidents, and develop, implement, and track any corrective actions found necessary to address an investigation's finding(s).

(n) *Safety data acquisition.* Each railroad establish and shall set forth a statement in its SSP plan that describes the processes it uses to collect, maintain, analyze, and distribute safety data in support of the system safety program.

(o) *Contract procurement requirements.* Each railroad shall set forth a statement in its SSP plan that describes the process(es) used to help ensure that safety concerns and hazards are adequately addressed during the safety-related contract procurement process.

(p) *Risk-based hazard management program.* Each railroad shall establish a risk-based hazard management program as part of the railroad's system safety program. The risk-based hazard management program shall be fully described in the SSP plan.

(1) The risk-based hazard management program shall establish:

(i) The processes or procedures used in the risk-based hazard analysis to identify hazards on the railroad's system;

(ii) The processes or procedures used in the risk-based hazard analysis to analyze identified hazards and support the risk-based hazard management program;

(iii) The methods used in the risk-based hazard analysis to determine the severity and frequency of hazards and to determine the corresponding risk;

(iv) The methods used in the risk-based hazard analysis to identify actions that mitigate or eliminate hazards and corresponding risks;

(v) The process for setting goals for the risk-based hazard management program and how performance against the goals will be reported;

(vi) The process to make decisions that affect the safety of the rail system relative to the risk-based hazard management program;

(vii) The methods used in the risk-based hazard management program to support continuous safety improvement throughout the life of the rail system; and

(viii) The methods used to maintain records of identified hazards and risks and the mitigation or elimination of the identified hazards and risks throughout the life of the rail system.

(2) The railroad's description of the risk-based hazard management program shall include:

(i) The position title of the individual(s) responsible for administering the risk-based hazard management program;

(ii) The identities of stakeholders who will participate in the risk-based hazard management program; and

(iii) The position title of the participants and structure of any hazard management teams or safety committees that a railroad may establish to support the risk-based hazard management program.

(q) *Risk-based hazard analysis.* (1) Once FRA approves a railroad's SSP plan pursuant to § 270.201(b), the railroad shall apply the risk-based hazard analysis methodology identified in paragraphs (p)(1)(i) through (iii) of this section to identify and analyze hazards on the railroad system and to determine the resulting risks. At a minimum, the aspects of the railroad system that shall be analyzed include: Operating rules and practices, infrastructure, equipment, employee levels and schedules, management structure, employee training, and other aspects that have an impact on railroad safety not covered by railroad safety regulations or other Federal regulations.

(2) A risk-based hazard analysis shall identify and the railroad shall implement specific actions using the methods described in paragraph (p)(1)(iv) of this section that will mitigate or eliminate the hazards and resulting risks identified by paragraph (q)(1) of this section.

(3) A railroad shall also conduct a risk-based hazard analysis pursuant to paragraphs (q)(1) and (2) of this section when there are significant operational changes, system extensions, system modifications, or other circumstances that have a direct impact on railroad safety.

(r) *Technology analysis and implementation plan.* (1) A railroad shall develop, and periodically update as necessary, a technology analysis and implementation plan as described by this paragraph. The railroad shall include this technology analysis and implementation plan in its SSP plan.

(2) A railroad's technology analysis and implementation plan shall describe the process the railroad will use to:

(i) Identify and analyze current, new, or novel technologies that will mitigate or eliminate the hazards and resulting risks identified by the risk-based hazard analysis pursuant to paragraph (q)(1) of this section; and

(ii) Analyze the safety impact, feasibility, and costs and benefits of implementing the technologies identified by the processes under paragraph (r)(2)(i) of this section that will mitigate or eliminate hazards and the resulting risks.

(3) Once FRA approves a railroad's SSP plan pursuant to § 270.201(b), including the technology analysis and implementation plan, the railroad shall apply:

(i) The processes described in paragraph (r)(2)(i) of this section to identify and analyze technologies that will mitigate or eliminate the hazards and resulting risks identified by the risk-based hazard analysis pursuant to paragraph (q)(1) of this section. At a minimum, the technologies a railroad shall consider as part of its technology analysis are: Processor-based technologies, positive train control systems, electronically-controlled pneumatic brakes, rail integrity inspection systems, rail integrity warning systems, switch position monitors and indicators, trespasser prevention technology, and highway-rail grade crossing warning and protection technology; and

(ii) The processes described in paragraph (r)(2)(ii) of this section to the technologies identified by the analysis under paragraph (r)(3)(i) of this section.

(4) If a railroad decides to implement any of the technologies identified in paragraph (r)(3) of this section, in the technology analysis and implementation plan in the SSP plan, the railroad shall:

(i) Describe how it will develop, adopt, implement, maintain, and use the identified technologies; and

(ii) Set forth a prioritized implementation schedule for the development, adoption, implementation and maintenance of those technologies over a 10-year period.

(5) Except as required by subpart I of part 236 of this chapter, if a railroad decides to implement a positive train control system as part of its technology analysis and implementation plan, the railroad shall set forth and comply with a schedule for implementation of the positive train control system consistent with the deadlines in the Positive Train Control Enforcement and Implementation Act of 2015, Public Law 114–73, 129 Stat. 576–82 (Oct. 29, 2015), and 49 CFR 236.1005(b)(7).

(6) The railroad shall not include in its SSP plan the analysis conducted pursuant to paragraph (r)(3) of this section. The railroad shall make the results of any analysis conducted pursuant to paragraph (r)(3) of this section available upon request to representatives of FRA and States participating under part 212 of this chapter.

(s) *Safety Assurance*—(1) *Change management.* Each railroad shall establish and set forth a statement in its SSP plan describing the processes and procedures used by the railroad to manage significant operational changes, system extensions, system modifications, or other significant changes that will have a direct impact on railroad safety.

(2) *Configuration management.* Each railroad shall establish a configuration management program and describe the program in its SSP plan. The configuration management program shall—

(i) Identify who within the railroad has authority to make configuration changes;

(ii) Establish processes to make configuration changes to the railroad's system; and

(iii) Establish processes to ensure that all departments of the railroad affected by the configuration changes are formally notified and approve of the change.

(3) *Safety certification.* Each railroad shall establish and set forth a statement in its SSP plan that describes the certification process used by the railroad to help ensure that safety concerns and hazards are adequately addressed before the initiation of operations or major projects to extend, rehabilitate, or modify an existing system or replace vehicles and equipment.

(t) *Safety culture.* A railroad shall set forth a statement in its SSP plan that describes how it measures the success of its safety culture identified in paragraph (b)(2) of this section.

§ 270.105 Discovery and admission as evidence of certain information.

(a) *Protected information.* Any information compiled or collected after August 14, 2017, solely for the purpose of planning, implementing, or evaluating a system safety program under this part shall not be subject to discovery, admitted into evidence, or considered for other purposes in a Federal or State court proceedings for damages involving personal injury, wrongful death, or property damage. For purposes of this section—

(1) "Information" includes plans, reports, documents, surveys, schedules, lists, or data, and specifically includes a railroad's analysis of its safety risks under § 270.103(q)(1) and a railroad's statement of mitigation measures under § 270.103(q)(2); and

(2) "Solely" means that a railroad originally compiled or collected the information for the exclusive purpose of planning, implementing, or evaluating a system safety program under this part. Information compiled or collected for any other purpose is not protected, even if the railroad also uses that information for a system safety program. "Solely" also means that a railroad continues to use that information only for its system safety program. If a railroad subsequently uses for any other purpose information that was initially compiled or collected for a system safety program, this section does not protect that information to the extent that it is used for the non-system safety program purpose. The use of that information within the railroad's system safety program, however, remains protected. This section does not protect information that is required to be compiled or collected pursuant to any other provision of law or regulation.

(b) *Non-protected information.* This section does not affect the discovery, admissibility, or consideration for other purposes in a Federal or State court proceedings for damages involving personal injury, wrongful death, or property damage of information compiled or collected for a purpose other than that specifically identified in paragraph (a) of this section. Such information shall continue to be discoverable, admissible, or considered for other purposes in a Federal or State court proceedings for damages involving personal injury, wrongful death, or property damage if it was discoverable, admissible, or considered for other purposes in a Federal or State court proceedings for damages involving personal injury, wrongful death, or property damage on or before August 14, 2017. Specifically, the types of information not affected by this section include:

(1) Information compiled or collected on or before August 14, 2017;

(2) Information compiled or collected on or before August 14, 2017, and that continues to be compiled or collected, even if used to plan, implement, or evaluate a railroad's system safety program; or

(3) Information that is compiled or collected after August 14, 2017, and is compiled or collected for a purpose other than that identified in paragraph (a) of this section.

(c) *Information protected by other law or regulation.* Nothing in this section shall affect or abridge in any way any other protection of information provided by another provision of law or regulation. Any such provision of law or regulation applies independently of the protections provided by this section.

(d) *Preemption.* To the extent that State discovery rules and sunshine laws would require disclosure of information protected by this section in a Federal or State court proceedings for damages involving personal injury, wrongful death, or property damage, those rules and laws are preempted.

§ 270.107 Consultation requirements.

(a) *General duty.* (1) Each railroad required to establish a system safety program under this part shall in good faith consult with, and use its best efforts to reach agreement with, all of its directly affected employees, including any non-profit labor organization representing a class or craft of directly affected employees, on the contents of the SSP plan.

(2) A railroad that consults with such a non-profit employee labor organization as required by paragraph (a)(1) of this section is considered to have consulted with the directly affected employees represented by that organization. If a railroad contracts out significant portions of its operations, the contractor and the contractor's employees performing the railroad's operations shall be considered directly affected employees for the purposes of this part.

(3) A railroad shall have a preliminary meeting with its directly affected employees to discuss how the consultation process will proceed. A railroad is not required to discuss the substance of a SSP plan during this preliminary meeting. A railroad must:

(i) Hold the preliminary meeting no later than April 10, 2017; and

(ii) Notify the directly affected employees of the preliminary meeting no less than 60 days before it is held.

(4) Appendix B to this part contains non-mandatory guidance on how a railroad may comply with the requirements of this section.

(b) *Railroad consultation statements.* A railroad required to submit a SSP plan under § 270.201 must also submit, together with the plan, a consultation statement that includes the following information:

(1) A detailed description of the process the railroad utilized to consult with its directly affected employees;

(2) If the railroad could not reach agreement with its directly affected employees on the contents of its SSP plan, identification of any known areas of disagreement and an explanation of why it believes agreement was not reached; and

(3) A service list containing the name and contact information for each international/national president of any non-profit employee labor organization representing a class or craft of the railroad's directly affected employees. The service list must also contain the name and contact information for any directly affected employee who significantly participated in the consultation process independently of a non-profit employee labor organization. When a railroad submits its SSP plan and consultation statement to FRA pursuant to § 270.201, it must also simultaneously send a copy of these documents to all individuals identified in the service list.

(c) *Statements from directly affected employees.* (1) If a railroad and its directly affected employees cannot reach agreement on the proposed contents of a SSP plan, the directly affected employees may file a statement with the FRA Associate Administrator for Railroad Safety and Chief Safety Officer explaining their views on the plan on which agreement was not reached with the FRA Associate Administrator for Railroad Safety and Chief Safety Officer at Mail Stop 25, 1200 New Jersey Ave SE., Washington, DC 20590. The FRA Associate Administrator for Railroad Safety and Chief Safety Officer shall consider any such views during the plan review and approval process.

(2) A railroad's directly affected employees have 30 days following the date of the railroad's submission of a proposed SSP plan to submit the statement described in paragraph (c)(1) of this section.

(d) *Consultation requirements for system safety program plan amendments.* A railroad's SSP plan must include a description of the process the railroad will use to consult with its directly affected employees on any subsequent substantive amendments to the railroad's system safety program. The requirements of this paragraph do not apply to non-substantive amendments (*e.g.,* amendments that update names and addresses of railroad personnel).

Subpart C—Review, Approval, and Retention of System Safety Program Plans

§ 270.201 Filing and approval.

(a) *Filing.* (1) Each railroad to which this part applies shall submit one copy of its SSP plan to the FRA Associate Administrator for Railroad Safety and Chief Safety Officer, Mail Stop 25, 1200 New Jersey Avenue SE., Washington, DC 20590, no later than February 8, 2018 or not less than 90 days before commencing operations, whichever is later.

(2) The railroad shall not include in its SSP plan the risk-based hazard analysis conducted pursuant to § 270.103(q). The railroad shall make the results of any risk-based hazard analysis available upon request to representatives of FRA and States participating under part 212 of this chapter.

(3) The SSP plan shall include:

(i) The signature, name, title, address, and telephone number of the chief safety officer who bears primary managerial authority for implementing the program for the submitting railroad. By signing, this chief official is certifying that the contents of the SSP plan are accurate and that the railroad will implement the contents of the program as approved by FRA;

(ii) The contact information for the primary person responsible for managing the system safety program; and

(iii) The contact information for the senior representatives of any host railroad, contract operator, shared track/corridor operator or persons utilizing or providing significant safety-related services.

(4) As required by § 270.107(b), each railroad must submit with its SSP plan a consultation statement describing how it consulted with its directly affected employees on the contents of its system safety program plan. Directly affected employees may also file a statement in accordance with § 270.107(c).

(b) *Approval.* (1) Within 90 days of receipt of a SSP plan, FRA will review the SSP plan to determine if the elements prescribed in this part are sufficiently addressed in the railroad's submission. This review will also consider any statement submitted by directly affected employees pursuant to § 270.107(c).

(2) FRA will notify each person identified by the railroad in § 270.201(a)(3) in writing whether the proposed plan has been approved by FRA, and, if not approved, the specific points in which the SSP plan is deficient. FRA will also provide this notification to each individual identified in the service list accompanying the consultation statement required under § 270.107(b).

(3) If FRA does not approve a SSP plan, the affected railroad shall amend the proposed plan to correct all deficiencies identified by FRA and provide FRA with a corrected copy of the SSP plan not later than 90 days following receipt of FRA's written notice that the proposed SSP plan was not approved.

(4) Approval of a railroad's SSP plan under this part does not constitute approval of the specific actions the railroad will implement under its SSP plan pursuant to § 270.103(q)(2) and shall not be construed as establishing a Federal standard regarding those specific actions.

(c) *Review of amendments.* (1)(i) A railroad shall submit any amendment(s) to the SSP plan to FRA not less than 60 days before the proposed effective date of the amendment(s). The railroad shall file the amended SSP plan with a cover letter outlining the changes made to the original approved SSP plan by the proposed amendment(s). The cover letter shall also describe the process the railroad used pursuant to § 270.107(d) to consult with its directly affected employees on the amendment(s).

(ii) If an amendment is safety-critical and the railroad is unable to submit the amended SSP plan to FRA 60 days before the proposed effective date of the amendment, the railroad shall submit the amended SSP plan with a cover letter outlining the changes made to the original approved SSP plan by the proposed amendment(s) and why the amendment is safety-critical to FRA as near as possible to 60 days before the proposed effective date of the amendment(s).

(iii) If the proposed amendment is limited to adding or changing a name, title, address, or telephone number of a person, FRA approval is not required under the process in paragraphs (c)(1)(i) and (ii) of this section, although the railroad shall still file the proposed amendment with FRA's Associate

Administrator for Railroad Safety and Chief Safety Officer. These proposed amendments may be implemented by the railroad upon filing with FRA. All other proposed amendments must comply with the formal approval process in paragraph (c) of this section.

(2)(i) Except as provided in paragraph (c)(1)(iii) of this section, FRA will review the proposed amended SSP plan within 45 days of receipt. FRA will then notify the primary contact person of each affected railroad whether the proposed amended plan has been approved by FRA, and if not approved, the specific points in which each proposed amendment to the SSP plan is deficient.

(ii) If FRA has not notified the railroad by the proposed effective date of the amendment(s) whether the proposed amended plan has been approved or not, the railroad may implement the amendment(s) pending FRA's decision.

(iii) If a proposed SSP plan amendment is not approved by FRA, no later than 60 days following the receipt of FRA's written notice, the railroad shall provide FRA either a corrected copy of the amendment that addresses all deficiencies noted by FRA or written notice that the railroad is retracting the amendment.

(d) *Reopened review.* Following initial approval of a plan, or amendment, FRA may reopen consideration of the plan or amendment for cause stated.

(e) *Electronic submission.* All documents required to be submitted to FRA under this part may be submitted electronically. Appendix C to this part provides instructions on electronic submission of documents.

§ 270.203 Retention of system safety program plan.

Each railroad to which this part applies shall retain at its system headquarters, and at any division headquarters, one copy of the SSP plan required by this part and one copy of each subsequent amendment to that plan. These records shall be made available to representatives of FRA and States participating under part 212 of this chapter for inspection and copying during normal business hours.

Subpart D—System Safety Program Internal Assessments and External Auditing

§ 270.301 General.

The system safety program and its implementation shall be assessed internally by the railroad and audited externally by FRA or FRA's designee.

§ 270.303 Internal system safety program assessment.

(a) Following FRA's initial approval of the railroad's SSP plan pursuant to § 270.201, the railroad shall annually conduct an assessment of the extent to which:

(1) The system safety program is fully implemented;

(2) The railroad is in compliance with the implemented elements of the approved system safety program; and

(3) The railroad has achieved the goals set forth in § 270.103(c).

(b) As part of its SSP plan, the railroad shall set forth a statement describing the processes used to:

(1) Conduct internal system safety program assessments;

(2) Internally report the findings of the internal system safety program assessments;

(3) Develop, track, and review recommendations as a result of the internal system safety program assessments;

(4) Develop improvement plans based on the internal system safety program assessments. Improvement plans shall, at a minimum, identify who is responsible for carrying out the necessary tasks to address assessment findings and specify a schedule of target dates with milestones to implement the improvements that address the assessment findings; and

(5) Manage revisions and updates to the SSP plan based on the internal system safety program assessments.

(c)(1) Within 60 days of completing its internal SSP plan assessment pursuant to paragraph (a) of this section, the railroad shall:

(i) Submit to FRA a copy of the railroad's internal assessment report that includes a system safety program assessment and the status of internal assessment findings and improvement plans to the FRA Associate Administrator for Railroad Safety and Chief Safety Officer, Mail Stop 25, 1200 New Jersey Avenue SE., Washington, DC 20590; and

(ii) Outline the specific improvement plans for achieving full implementation of the SSP plan, as well as achieving the goals of the plan.

(2) The railroad's chief official responsible for safety shall certify the results of the railroad's internal SSP plan assessment.

§ 270.305 External safety audit.

(a) FRA may conduct, or cause to be conducted, external audits of a railroad's system safety program. Each audit will evaluate the railroad's compliance with the elements required by this part in the railroad's approved SSP plan. FRA shall provide the railroad written notification of the results of any audit.

(b)(1) Within 60 days of FRA's written notification of the results of the audit, the railroad shall submit to FRA for approval an improvement plan to address the audit findings that require corrective action. At a minimum, the improvement plan shall identify who is responsible for carrying out the necessary tasks to address audit findings and specify target dates and milestones to implement the improvements that address the audit findings.

(2) If FRA does not approve the railroad's improvement plan, FRA will notify the railroad of the specific deficiencies in the improvement plan. The affected railroad shall amend the proposed plan to correct the deficiencies identified by FRA and provide FRA with a corrected copy of the improvement plan no later than 30 days following its receipt of FRA's written notice that the proposed plan was not approved.

(3) Upon request, the railroad shall provide to FRA and States participating under part 212 of this chapter for review a report upon request regarding the status of the implementation of the improvements set forth in the improvement plan established pursuant to paragraph (b)(1) of this section.

Appendix A to Part 270—Schedule of Civil Penalties

PENALTY SCHEDULE [1]

	Violation	Willful violation
Subpart B—System Safety Program Requirements		
270.101—System safety program; general:		
(a) Failure to establish a system safety program	$15,000	$30,000
(a) Failure to include a risk-based hazard management program in the railroad's system safety program	10,000	20,000
270.103—System safety program plan:		

PENALTY SCHEDULE [1]—Continued

	Violation	Willful violation
(a)(1) Failure to include and comply with any required element or any sub-element in the SSP plan	7,500	15,000
(a)(2) Failure to communicate and coordinate with host railroad on the SSP plan	7,500	15,000
270.107—Consultation Requirements:		
(a)(1) Failure to consult with directly affected employees	10,000	20,000
Failure to consult in good faith and/or use best efforts	10,000	20,000
(a)(3) Failure to hold preliminary meeting	7,500	15,000
Failure to hold preliminary meeting within April 10, 2017	5,000	10,000
Failure to notify directly affected employees no less than 60 days before meeting is held	7,500	15,000
(b) Failure to submit consultation statement with plan submission	7,500	15,000
Failure to include all required elements in consultation statement	5,000	10,000
(d) Failure to submit consultation statement with submission of plan amendment	5,000	10,000
Subpart C—Review, Approval, and Retention of SSP Plans		
270.201—Filing and approval:		
(a)(1) Failure to file an initial SSP plan	10,000	20,000
Failure to file a SSP plan within 90 days of commencing operations	10,000	20,000
(a)(3) Failure to include all required information in submission	5,000	10,000
(b)(3) Failure to correct identified deficiencies and amend SSP plan	7,500	15,000
Failure to submit amended SSP plan	7,500	15,000
Failure to submit amended SSP plan within 90 days	5,000	10,000
(c)(1)(i) Failure to submit amendment to SSP plan	7,500	15,000
Failure to submit amendment to SSP plan within 60 days	5,000	10,000
(c)(2)(iii) Failure to submit corrected amendment or notify FRA of retraction	7,500	15,000
Failure to submit corrected amendment within 60 days	5,000	10,000
270.203—Retention of SSP plan:		
Failure to retain a copy of the SSP plan at the system/division headquarters	10,000	20,000
Failure to make records available to representatives of FRA and States participating under part 212 of this chapter	7,500	15,000
Subpart D—System Safety Program Internal Assessments and External Auditing		
270.303—Internal program assessment:		
(a) Failure to conduct an annual internal assessment	10,000	20,000
Failure to include all required elements in the internal assessment	7,500	15,000
(b) Failure to include a statement in the SSP plan describing the required elements	5,000	10,000
(c)(1)(i) Failure to submit to FRA the internal assessment report	7,500	15,000
Failure for the internal assessment report to contain all required elements and sub-elements	5,000	10,000
(c)(1)(ii) Failure to develop and outline improvement plans	7,500	15,000
Failure to comply with improvement plans	7,500	15,000
(c)(2) Failure of chief official responsible for safety to certify the results of the internal assessment	5,000	10,000
270.305—External safety audit:		
(b)(1) Failure to submit improvement plans	7,500	15,000
Failure to submit improvement plans within 60 days	5,000	10,000
Failure to include all required elements in the improvement plans	5,000	10,000
(b)(2) Failure to amend and submit to FRA the improvement plan	7,500	15,000
Failure to submit amended improvement plan within 30 days	5,000	10,000
(b)(3) Failure to provide a report regarding the status of the implementation of the improvements set forth in the improvement plan	7,500	15,000

[1] A penalty may be assessed against an individual only for a willful violation. The Administrator reserves the right to assess a penalty of up to $109,819 for any violation where circumstances warrant. See 49 CFR part 209, appendix A.

Appendix B to Part 270—Federal Railroad Administration Guidance on the System Safety Program Consultation Process

A railroad required to develop a system safety program under this part must in good faith consult with and use its best efforts to reach agreement with its directly affected employees on the contents of the SSP plan. *See* § 270.107(a). This appendix discusses the meaning of the terms "good faith" and "best efforts," and provides non-mandatory guidance on how a railroad may comply with the requirement to consult with directly affected employees on the contents of its SSP plan. Guidance is provided for employees who are represented by a non-profit employee labor organization and employees who are not represented by any such organization.

The Meaning of "Good Faith" and "Best Efforts"

"Good faith" and "best efforts" are not interchangeable terms representing a vague standard for the § 270.107 consultation process. Rather, each term has a specific and distinct meaning. When consulting with directly affected employees, therefore, a railroad must independently meet the standards for both the good faith and best efforts obligations. A railroad that does not meet the standard for one or the other will not be in compliance with the consultation requirements of § 270.107.

The good faith obligation requires a railroad to consult with employees in a manner that is honest, fair, and reasonable, and to genuinely pursue agreement on the contents of a SSP plan. If a railroad consults with its employees merely in a perfunctory manner, without genuinely pursuing agreement, it will not have met the good faith requirement. For example, a lack of good faith may be found if a railroad's directly affected employees express concerns with certain parts of the railroad's SSP plan, and the railroad neither addresses those concerns in further consultation nor attempts to address those concerns by making changes to the SSP plan.

On the other hand, "best efforts" establishes a higher standard than that imposed by the good faith obligation, and describes the diligent attempts that a railroad must pursue to reach agreement with its employees on the contents of its system safety program. While the good faith obligation is concerned with the railroad's state of mind during the consultation process, the best efforts obligation is concerned with the specific efforts made by the railroad in an attempt to reach agreement. This would include considerations such as whether a railroad had held sufficient meetings with its employees to address or make an attempt to address any concerns raised by the employees, or whether the railroad had made an effort to respond to feedback provided by employees during the consultation process. For example, a railroad would not meet the best efforts obligation if it did not initiate the consultation process in a timely manner, and thereby failed to provide employees sufficient time to engage in the consultation process. A railroad may, however, wish to hold off substantive consultations regarding the contents of its SSP until one year after the publication date of the rule to ensure that certain information generated as part of the process is protected from discovery and admissibility into evidence under § 270.105 of the rule. Generally, best efforts are measured by the measures that a reasonable person in the same circumstances and of the same nature as the acting party would take. Therefore, the standard imposed by the best efforts obligation may vary with different railroads, depending on a railroad's size, resources, and number of employees.

When reviewing SSP plans, FRA will determine on a case-by-case basis whether a railroad has met its § 270.107 good faith and best efforts obligations. This determination will be based upon the consultation statement submitted by the railroad pursuant to § 270.107(b) and any statements submitted by employees pursuant to § 270.107(c). If FRA finds that these statements do not provide sufficient information to determine whether a railroad used good faith and best efforts to reach agreement, FRA may investigate further and contact the railroad or its employees to request additional information. If FRA determines that a railroad did not use good faith and best efforts, FRA may disapprove the SSP plan submitted by the railroad and direct the railroad to comply with the consultation requirements of § 270.107. Pursuant to § 270.201(b)(3), if FRA does not approve the SSP plan, the railroad will have 90 days, following receipt of FRA's written notice that the plan was not approved, to correct any deficiency identified. In such cases, the identified deficiency would be that the railroad did not use good faith and best efforts to consult and reach agreement with its directly affected employees. If a railroad then does not submit to FRA within 90 days a SSP plan meeting the consultation requirements of § 270.107, the railroad could be subject to penalties for failure to comply with § 270.201(b)(3).

Guidance on How a Railroad May Consult With Directly Affected Employees

Because the standard imposed by the best efforts obligation will vary depending upon the railroad, there may be countless ways for various railroads to comply with the consultation requirements of § 270.107. Therefore, FRA believes it is important to maintain a flexible approach to the § 270.107 consultation requirements, to give a railroad and its directly affected employees the freedom to consult in a manner best suited to their specific circumstances.

FRA is nevertheless providing guidance in this appendix as to how a railroad may proceed when consulting (utilizing good faith and best efforts) with employees in an attempt to reach agreement on the contents of a SSP plan. FRA believes this guidance may be useful as a starting point for railroads that are uncertain about how to comply with the § 270.107 consultation requirements. This guidance distinguishes between employees who are represented by a non-profit employee labor organization and employees who are not, as the processes a railroad may use to consult with represented and non-represented employees could differ significantly.

This guidance does not establish prescriptive requirements with which a railroad must comply, but merely outlines a consultation process a railroad may choose to follow. A railroad's consultation statement could indicate that the railroad followed the guidance in this appendix as evidence that it utilized good faith and best efforts to reach agreement with its employees on the contents of a SSP plan.

Employees Represented by a Non-Profit Employee Labor Organization

As provided in § 270.107(a)(2), a railroad consulting with the representatives of a non-profit employee labor organization on the contents of a SSP plan will be considered to have consulted with the directly affected employees represented by that organization.

A railroad may utilize the following process as a roadmap for using good faith and best efforts when consulting with represented employees in an attempt to reach agreement on the contents of a SSP plan.

- Pursuant to § 270.107(a)(3)(i), a railroad must meet with representatives from a non-profit employee labor organization (representing a class or craft of the railroad's directly affected employees) no later than April 10, 2017, to begin the process of consulting on the contents of the railroad's SSP plan. A railroad must provide notice at least 60 days before the scheduled meeting.
- During the time between the initial meeting and the applicability date of § 270.105 the parties may meet to discuss administrative details of the consultation process as necessary.
- Within 60 days after the applicability date of § 270.105 a railroad should have a meeting with the directed affected employees to discuss substantive issues with the SSP.
- Pursuant to § 270.201(a)(1), a railroad would file its SSP plan with FRA no later than February 8, 2018, or not less than 90 days before commencing operations, whichever is later.
- As provided by § 270.107(c), if agreement on the contents of a SSP plan could not be reached, a labor organization (representing a class or craft of the railroad's directly affected employees) may file a statement with the FRA Associate Administrator for Railroad Safety and Chief Safety Officer explaining its views on the plan on which agreement was not reached.

Employees Who Are Not Represented by a Non-Profit Employee Labor Organization

FRA recognizes that some (or all) of a railroad's directly affected employees may not be represented by a non-profit employee labor organization. For such non-represented employees, the consultation process described for represented employees may not be appropriate or sufficient. For example, FRA believes that a railroad with non-represented employees should make a concerted effort to ensure that its non-represented employees are aware that they are able to participate in the development of the railroad's SSP plan. FRA therefore is providing the following guidance regarding how a railroad may utilize good faith and best efforts when consulting with non-represented employees on the contents of its SSP plan.

- By December 12, 2016 (*i.e.*, within 60 days of the effective date of the final rule), a railroad may notify non-represented employees that—

(1) The railroad is required to consult in good faith with, and use its best efforts to reach agreement with, all directly affected employees on the proposed contents of its SSP plan;

(2) The railroad is required to meet with its directly affected employees within 180 days of the effective date of the final rule to address the consultation process;

(3) Non-represented employees are invited to participate in the consultation process (and include instructions on how to engage in this process); and

(4) If a railroad is unable to reach agreement with its directly affected employees on the contents of the proposed SSP plan, an employee may file a statement with the FRA Associate Administrator for Railroad Safety and Chief Safety Officer explaining his or her views on the plan on which agreement was not reached.

- This initial notification (and all subsequent communications, as necessary or appropriate) could be provided to non-represented employees in the following ways:

(1) Electronically, such as by email or an announcement on the railroad's Web site;

(2) By posting the notification in a location easily accessible and visible to non-represented employees; or

(3) By providing all non-represented employees a hard copy of the notification. A railroad could use any or all of these methods of communication, so long as the notification complies with the railroad's obligation to utilize best efforts in the consultation process.

- Following the initial notification and initial meeting to discuss the consultation process (and before the railroad submits its SSP plan to FRA), a railroad should provide non-represented employees a draft proposal of its SSP plan. This draft proposal should solicit additional input from non-represented employees, and the railroad should provide non-represented employees 60 days to submit comments to the railroad on the draft.

- Following this 60-day comment period and any changes to the draft SSP plan made as a result, the railroad should submit the proposed SSP plan to FRA, as required by this part.
- As provided by § 270.107(c), if agreement on the contents of a SSP plan cannot be reached, then a non-represented employee may file a statement with the FRA Associate Administrator for Railroad Safety and Chief Safety Officer explaining his or her views on the plan on which agreement was not reached.

Appendix C to Part 270—Procedures for Submission of SSP Plans and Statements From Directly Affected Employees

This appendix establishes procedures for the submission of a railroad's SSP plan and statements by directly affected employees consistent with the requirements of this part.

Submission by a Railroad and Directly Affected Employees

As provided for in § 270.101, a system safety program shall be fully implemented and supported by a written SSP plan. Each railroad must submit its SSP plan to FRA for approval as provided for in § 270.201.

As provided for in § 270.107(c), if a railroad and its directly affected employees cannot come to agreement on the proposed contents of the railroad's SSP plan, the directly affected employees have 30 days following the railroad's submission of its proposed SSP plan to submit a statement to the FRA Associate Administrator for Railroad Safety and Chief Safety Officer explaining the directly affected employees' views on the plan on which agreement was not reached.

The railroad's and directly affected employees' submissions shall be sent to the FRA Associate Administrator for Railroad Safety and Chief Safety Officer, Mail Stop 25, 1200 New Jersey Avenue SE., Washington, DC 20590. When a railroad submits its SSP plan and consultation statement to FRA pursuant to § 270.201, it must also simultaneously send a copy of these documents to all individuals identified in the service list pursuant to § 270.107(b)(3).

Each railroad and directly affected employee is authorized to file by electronic means any submissions required under this part. Before any person submitting anything electronically, the person shall provide the FRA Associate Administrator for Railroad Safety and Chief Safety Officer with the following information in writing:

(1) The name of the railroad or directly affected employee(s);

(2) The names of two individuals, including job titles, who will be the railroad's or directly affected employees' points of contact and will be the only individuals allowed access to FRA's secure document submission site;

(3) The mailing addresses for the railroad's or directly affected employees' points of contact;

(4) The railroad's system or main headquarters address located in the United States;

(5) The email addresses for the railroad's or directly affected employees' points of contact; and

(6) The daytime telephone numbers for the railroad's or directly affected employees' points of contact.

A request for electronic submission or FRA review of written materials shall be addressed to the FRA Associate Administrator for Railroad Safety and Chief Safety Officer, Mail Stop 25, 1200 New Jersey Avenue SE., Washington, DC 20590. Upon receipt of a request for electronic submission that contains the information listed above, FRA will then contact the requestor with instructions for electronically submitting its program or statement. A railroad that electronically submits an initial SSP plan or new portions or revisions to an approved program required by this part shall be considered to have provided its consent to receive approval or disapproval notices from FRA by email. FRA may electronically store any materials required by this part regardless of whether the railroad that submits the materials does so by delivering the written materials to the Associate Administrator and opts not to submit the materials electronically. A railroad that opts not to submit the materials required by this part electronically, but provides one or more email addresses in its submission, shall be considered to have provided its consent to receive approval or disapproval notices from FRA by email or mail.

Issued in Washington, DC, pursuant to the authority delegated under 49 CFR 1.89(b).

Sarah E. Feinberg,

Administrator.

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